In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-1024V

(to be published)

* *	Chief Special Master Corcoran
M.R., *	
*	
Petitioner, *	Dated: June 30, 2023
*	
v. *	
*	
SECRETARY OF HEALTH AND HUMAN SERVICES, *	
*	
Respondent. *	
*	
* *	

Ronald Craig Homer, Conway Homer, P.C., Boston, MA, for Petitioner.

Sarah Black Rifkin, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION ON REMAND DISMISSING CASE[1]

On August 18, 2016, M.R. filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Program").[2] ECF No. 1. Petitioner alleges that an influenza ("flu") vaccination administered to him on October 21, 2014, caused him to experience left-sided sudden sensorineural hearing loss ("SNHL"). An entitlement hearing in the matter was held on February 25, 2022, in Washington, D.C.

After review of the record, all expert reports and associated literature, and hearing the witnesses who testified at trial, I initially denied entitlement, based on the determination

[1] This Decision will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published Ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

Petitioner's evidentiarily-established acoustic neuroma/vestibular schwannoma[3] was the most likely cause of his SNHL. But Petitioner sought review of the initial Decision, and succeeded in having it vacated and remanded for a more thorough analysis of several matters. *See* Order, dated March, 27, 2023 (ECF No. 99) (the "Remand Order"). In particular, I was ordered to determine whether Respondent had carried his burden of demonstrating the neuroma was more likely than not the sole "substantial factor" for his hearing loss, and/or if the vaccine still could have been a substantial factor. Remand Order at 10–11.

I have now performed that analysis, after a complete review of the entire record a second time. For the reasons set forth below, I reach the same conclusion as before. The evidence preponderantly establishes that Petitioner's neuroma was more likely to have caused Petitioner's hearing loss than the flu vaccine (which has not preponderantly been shown to be capable of causing hearing loss in the first place—and thus could not also have likely been a substantial factor herein as causing hearing loss in conjunction with the neuroma).

I. Fact History

Vaccination and Onset of Symptoms

Petitioner was a forty-nine-year-old registered nurse when he received a flu vaccine in his left arm on October 21, 2014, at his place of employment, Robert Wood Johnson ("RWJ") University Hospital in New Brunswick, New Jersey. Pet. 1 at 1; Ex. 18 at 1 ("M.R. Affidavit"). His past medical history was significant for morbid obesity, urinary tract stone disease, allergic rhinitis, elevated cholesterol/triglycerides, and elevated hemoglobin A1C in 2013. Ex. 2 at 2–5, 8–10, 23–24; Ex. 3 at 3–4. Petitioner had also previously received flu vaccines at work for at least the prior three years, but with no reported adverse events. Ex. 12 at 15.[4] There is no contemporaneous record evidence of any immediate post-vaccination reaction (although as noted below, Petitioner *later* reported to treaters that he had in fact experienced some kind of reaction).

On October 27, 2014 (six days after vaccination), M.R. presented to the emergency room ("ER") of RWJ Hospital, "complaining of severe vertigo with hearing loss to the left ear." Ex. 7 at 113. Petitioner reported an "abrupt onset of painless vertigo beginning 2 days ago [on October

[3] An acoustic neuroma, also known as vestibular schwannoma, is "a progressively enlarging, benign tumor, usually within the internal auditory canal arising from Schwann cells of the vestibular division of the eighth cranial nerve; the symptoms, which vary with the size and location of the tumor, may include hearing loss, headache, disturbances of balance and gait, facial numbness or pain, and tinnitus. It may be unilateral or bilateral. . . ." *Acoustic Neuroma,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=92588 (last visited June 30, 2023). Herein, I will use the terms neuroma and vestibular schwannoma interchangeably.

[4] Petitioner had volunteered for a non-contrast brain magnetic resonance imaging ("MRI") in February 2003, which was unremarkable except for mild sinus mucosal thickening. Ex. 20 at 1.

25th] that ha[d] been intermittent until today." *Id.* An ER physician treated Petitioner with Meclizine, which provided a "good relief of symptoms." *Id.* at 114. A CT scan revealed no abnormalities, and the examination yielded results deemed within normal limits except for some horizontal nystagmus.[5] *Id.* at 115. Petitioner was diagnosed with acute labyrinthitis and discharged the same day. *Id.* at 113–14. The differential diagnoses included a cerebellopontine angle ("CPA") tumor. Tr. at 114–15

Petitioner next presented to otolaryngologist Michael Goldrich, M.D., on October 30, 2014, complaining of "symptoms of vertigo since Saturday [October 25]." Ex. 5 at 43. Petitioner reported hearing loss in his left ear and one episode of nausea and vomiting. *Id.* An audiogram from that same day revealed profound sensorineural hearing loss in petitioner's left ear. *Id.* at 46, 54–55. Dr. Goldrich's impression was acute hearing loss and vertigo. *Id.* at 46.

The following day, Dr. Goldrich performed a left myringotomy, tube insertion, and steroid instillation. Ex. 7 at 1, 15, 50. Dr. Goldrich noted that "5 days [after] flu vaccine on 10/21/14 [patient with] reports of hearing loss [in his left] ear." *Id.* at 25. Both the preoperative and postoperative diagnoses were eustachian tube dysfunction and acute SNHL in Petitioner's left ear. *Id.* at 50.

On November 3, 2014,[6] Petitioner saw Dr. Goldrich, whose continued assessment was that Petitioner had experienced acute hearing loss and vertigo. Ex. 5 at 40, 42. That same day, Petitioner had a hearing consultation with otolaryngology surgeon Jed Kwartler, M.D. Ex. 9 at 16. Petitioner indicated to Dr. Kwartler that his sudden hearing loss occurred about a week before. *Id.* He denied any recent viral illness, but mentioned that he had received the flu vaccine prior to the onset of his symptoms. *Id.* Petitioner's hearing test showed a profound left SNHL, with normal hearing in his right ear. *Id.* at 18. Dr. Kwartler diagnosed Petitioner with unspecified sudden hearing loss and hypoactive labyrinthine dysfunction. *Id.* He prescribed a Prednisone taper, discussed hyperbaric oxygen therapy, and ordered an MRI. *Id.*

Two days later, on November 5, 2014, Petitioner presented to the RWJ Center for Wound Healing for hyperbaric oxygen therapy. Ex. 16 at 1. He reported that he received "a flu shot at work [on] 10/21/2014 and stated he felt discomfort radiating up [the] left side of [his] neck and ear." *Id.* He also indicated that shortly after vaccination, he developed vertigo that initially lasted

[5] Nystagmus is defined as "an involuntary, rapid, rhythmic movement of the eyeball, which may be horizontal, vertical, rotatory, or mixed." *Nystagmus,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=34565&searchterm=nystagmus (last visited June 30, 2023).

[6] That same day, Petitioner filed a Vaccine Adverse Event Reporting System ("VAERS") report, and reportedly contacted the pharmaceutical manufacturer of the vaccine as well. Ex. 5 at 81; Ex. 12 at 1. VAERS is a database maintained by the Center for Disease Control ("CDC") to compile information from reports about reactions to immunizations listed on the Vaccine Injury Table, 42 U.S.C. § 300aa–14(a).

for five minutes and then dissipated on its own with severe dizziness. *Id.* He reported more episodes of vertigo the next day that were severe to the point of nausea and vomiting. *Id.* Petitioner stated that he felt like he was getting better, but still felt a little unbalanced. *Id.* The physician noted that Petitioner was "scheduled to have an MRI on Monday to make sure that there [wa]s no evidence of acoustic neuroma." *Id.* Petitioner received a trial of hyperbaric oxygen therapy at this visit and underwent a total of twenty-three hyperbaric oxygen treatments through December 15, 2014. *Id.* at 1, 51.

Discovery of Acoustic Neuroma

A November 10, 2014 brain MRI performed on M.R. revealed a "round 5 mm x 4 mm structure in the distal aspect of [Petitioner's] left internal auditory canal." Ex. 5 at 58. The neuroradiologist's impression was that the structure most likely represented a vestibular schwannoma. *Id.* Dr. Kwartler reviewed the MRI results with Petitioner on November 11, 2014. Ex. 9 at 13. Dr. Kwartler observed that the MRI showed "a left lateral internal auditory canal lesion consistent with an acoustic neuroma." *Id.* at 14. His assessment was unilateral SNHL and acoustic neuroma. *Id.* Petitioner agreed to hold off on additional treatment until he had completed his hyperbaric oxygen therapy. *Id.* Dr. Kwartler added that if Petitioner did not recover, "it might be reasonable to proceed with a translabyrinthine approach for tumor removal" or, alternatively, repeat Petitioner's "MRI in 6 months to monitor for any growth." *Id.*

M.R. continued to see Dr. Goldrich for follow-up visits through December 2014 for steroid instillation into his external auditory canal. Ex. 5 at 19, 31, 36, 40. Dr. Goldrich first referenced Petitioner's prior vaccination on November 6, 2014, noting Petitioner's medical history narrative reported that his "[s]ymptoms began 4 days after receiving Flu Vaccine." *Id.* at 36. Later, on November 12, 2014, Dr. Goldrich noted more specifically that Petitioner had "acute hearing loss and vertigo following Influenza vaccination." *Id.* at 33–34. However, during this visit he also included in the record the fact that an MRI had revealed "a small acoustic neuroma on the left [side]." *Id.* at 31. By November 20, 2014, Petitioner was reportedly doing well, experiencing no vertigo or disequilibrium. *Id.* at 23. Dr. Goldrich noted that an audiogram conducted that day showed "some improvement in bone conduction levels on the left." *Id.* However, a December 16, 2014, audiogram showed "no improvement in hearing on the left after 20+ treatments with hyperbaric oxygen." *Id.* at 19.

On December 22, 2014, Petitioner filed an employee accident/illness report with RWJ, reporting that approximately five days after his vaccination he had developed episodes of vertigo and hearing loss. *Id.* at 88. He related his symptoms to vaccination. *Id.* The following day, on December 23, 2014, Petitioner underwent a hearing aid evaluation. *Id.* at 71. His medical history indicated that Petitioner *himself* "suspect[ed] that he lost his hearing in the left ear following administration of the flu shot." *Id.*

On January 26, 2015, Petitioner returned to Dr. Kwartler to discuss hearing rehabilitation options. Ex. 9 at 10. In particular, they discussed a hearing aid—the attract bone-anchored hearing aid ("BAHA") system[7]—and Dr. Kwartler ordered another MRI. *Id.* at 11. At his March 11, 2015, follow-up with Dr. Goldrich, Petitioner reported "stable symptoms of disequilibrium and hearing loss" and expressed an interest in pursuing a BAHA fitting. Ex. 8 at 23.

Another brain MRI was performed on April 9, 2015, and it confirmed the existence of an intracanalicular left vestibular schwannoma, but otherwise no changes from the first MRI (conducted on November 10, 2014). Ex. 14 at 86. On April 17, 2015, Dr. Kwartler surgically placed petitioner's BAHA implant. Ex. 11 at 25. Petitioner had no complaints at his first post-operative visit six days later. Ex. 9 at 7. On May 11, 2015, he presented to Dr. Kwartler with a small amount of irritation along his incision, but this appeared to have cleared by May 27, 2015. *Id.* at 3, 5. He informed Dr. Goldrich at his June 23, 2015, follow-up visit that he had received a BAHA fitting and was doing well, with no new complaints. Ex. 8 at 27–28. However, on July 20, 2015, he "[d]iscussed issues related to tissue change around the magnet" with Dr. Kwartler. Ex. 9 at 1.

Petitioner underwent a third brain MRI on September 24, 2015, and it (again) revealed "a left intracanalicular mass measuring 6 mm unchanged compared to prior MRI of 4/9/2015 which is consistent with vestibular schwannoma. . . ." Ex. 15 at 4. On October 5, 2015, Petitioner reviewed this MRI with Dr. Kwartler, who indicated that there was no change in his tumor size." *Id.* at 2. Upon physical examination, Petitioner's "[m]agnet site remain[ed] nicely healed," his "cranial nerves intact," and his "gait [was] steady." *Id.* Dr. Kwartler's diagnosed Petitioner with acoustic neuroma and unilateral SNHL. *Id.*

New Hearing Aid System and Continued Care

In November 2015, Petitioner expressed interest in switching to a new hearing aid system due to tissue build-up at his implant site that was interfering with magnet retention. Ex. 13 at 3. On November 19, 2015, Petitioner presented to otolaryngologist Kianoush Sheykholeslami, M.D. for an evaluation for a new hearing aid system. *Id.* Petitioner reported that he lost his left-sided hearing four days after a flu shot. *Id.* Dr. Sheykholeslami noted that there was "[n]o change in hearing sensitivity," and recommended a follow-up to schedule the BAHA surgery. *Id.*

On December 17, 2015, Dr. Sheykholeslami revised Petitioner's BAHA device. Ex. 14 at 8; Ex. 17 at 4. His preoperative and postoperative diagnoses remained unchanged as left unilateral

[7] In January 2015, Petitioner also tried a different hearing aid system, but had difficulty in the cafeteria and places with loud noise, so he returned the device. Ex. 13 at 9.

deafness. Ex. 14 at 18. On December 24, 2015, Petitioner returned to Dr. Sheykholeslami, stating that he was doing very well. Ex. 17 at 2.

A repeat brain MRI was performed on March 31, 2016. As with the prior MRIs, it "reveal[ed] a 6 mm enhancing lesion in the left internal auditory canal . . . most consistent with a vestibular schwannoma." Ex. 17 at 1. Several months later, Petitioner saw Dr. Kwartler on September 26, 2016, complaining of left ear pressure. Ex. 26 at 5. Dr. Kwartler advised continued monitoring of the acoustic tumor, which had not changed in size. *Id*.

On February 14, 2017, Petitioner saw audiologist Laura Matlin, Au.D., for an annual hearing evaluation. Ex. 21 at 1. Dr. Matlin documented Petitioner's medical history, noting that in October 2014, "he reported a sudden hearing loss in the left ear 4 days following administration of the flu shot. . . . A subsequent MRI revealed evidence of a '5 mm' vestibular schwannoma in the left internal auditory canal." *Id*. Upon examination, Petitioner exhibited normal hearing across all frequencies in his right ear and profound sensorineural hearing loss in his left ear. *Id*. Petitioner requested increased volume in his hearing aid. *Id*. Dr. Matlin recommended regular monitoring of the left-sided vestibular schwannoma and annual audiologic exams to monitor petitioner's hearing. *Id*. at 2.

On July 3, 2018, Petitioner presented to his primary care provider ("PCP"), Dr. Brian Cassidy, for a comprehensive physical exam. Ex. 27 at 214. Dr. Cassidy noted:

> Since I last saw [Petitioner] he had an[] acoustic neuritis culminating in the need for a BAHA procedure on the left by Dr. Kwartler. It was felt[8] that it was related to an influenza immunization that he had been given and he has now gotten lifelong exemption for receiving further influenza immunizations.

Id.[9] Dr. Cassidy *did* recommend other vaccinations, however, including for tetanus, diphtheria, and pertussis, pneumonia, and shingles. Ex. 27 at 37. And during a February 16, 2021 visit, he "strongly advised [receipt of] the COVID vaccine." *Id*. at 8.

A repeat brain MRI performed on April 25, 2019, confirmed the presence of a stable 6 mm vestibular schwannoma. *Id*. at 171. On October 14, 2020, M.R. followed up with otolaryngologist P. Ashley Wackym, M.D., regarding his schwannoma. Ex. 25 at 1. Dr. Wackym reviewed Petitioner's June 11, 2020 brain MRI, which showed a "small left distal vestibular schwannoma that extends to the fundus of his internal auditory canal." *Id*. Dr. Wackym also reviewed Petitioner's August 25, 2020 audiogram, which confirmed that Petitioner remained deaf in his left

[8] There is no further description for the basis of this "feeling."

[9] Besides Dr. Goldrich, Petitioner also argues that Dr. Sheykholeslami (Dr. Wackym's former ENT partner) granted him lifetime immunity, though there is a lack of medical record documentation. Tr. at 16, 23.

ear. *Id*. Dr. Wackym discussed cochlear implantation, but Petitioner stated that his tinnitus was not bothersome. *Id*. Dr. Wackym recommended a repeat MRI and audiogram in one year. *Id*. Petitioner has since had stable left-sided vestibular schwannoma, and his last documented MRI occurred in July 2021. Ex. 31 at 11–17.

II. Witness Testimony

A. M.R.

Petitioner was the only fact witness to testify. *See generally* Tr. at 5–23. His testimony largely consisted of his recollection of symptom onset and treatment.

Prior to vaccination, Petitioner stated, he was in good health, active, and had a normal social life. Tr. at 6. He never experienced hearing loss or vestibular symptoms. *Id*. at 15. On October 21, 2014, Petitioner received the flu vaccine as a suggestion of a co-worker.[10] *Id*. at 7. He described the vaccination as "pretty much painless." *Id.* at 7. The following day he developed soreness at the injection site, and over the next four days he described the pain as travelling up his shoulder, to his neck, and eventually to his left ear. *Id.* at 7–8.

He began experiencing symptoms related to his hearing loss on October 25, 2014—four days post-vaccination—when he noticed sound becoming distant in his left ear followed by a sudden onset of vertigo lasting four to five minutes before clearing up.[11] Tr. at 8. The next day, he had two similar episodes of hearing loss in his left ear followed by vertigo, which lasted between three to five minutes before clearing up. *Id.* at 8.

On the morning of October 27, 2014, after arriving at work, Petitioner had another episode of hearing loss in his left ear followed by vertigo, but it did not dissipate as it had previously.[12] Tr. at 8. He was instructed by his supervisor to go to the ER. *Id*. at 9. There, Petitioner underwent a CAT scan to rule out a tumor or stroke, and was referred to an ear, nose, and throat specialist (Dr. Goldrich) who sent him for a myringotomy tube to distribute steroids, and in turn referred him to a neurotologist (Dr. Kwartler). *Id.* at 9–10. Dr. Kwartler increased Petitioner's steroids,

[10] In 2014, Petitioner was not required to get the flu shot for his job as a registered nurse. Tr. at 7, 21. As of the date of the hearing, Petitioner noted that it was required by his job, but he had a lifetime exemption granted by treaters due to his purported reaction from the flu vaccine at issue in this case. *Id.* at 16, 22.

[11] M.R.'s affidavit stated that his vertigo lasted about two minutes rather than four to five minutes. M.R. Affidavit at 2.

[12] By this point, Petitioner's vertigo had not dissipated for three to four weeks, and he lost all hearing in his left ear. Tr. at 8, 11.

recommended hyperbaric oxygen therapy,[13] and ordered an MRI. *Id.* at 10. The MRI found a small vestibular schwannoma or acoustic neuroma on the left side. *Id.* at 11.

Petitioner returned to work after three and a half to four weeks, but continued to experience vertigo. Tr. at 12. Following his return, he attended hyperbaric oxygen therapy three times a week for four to five weeks, and continued with steroids until the course was finished. *Id*. At that point, Petitioner's hearing in his left ear had not yet returned. *Id.*

Because traditional hearing aids do not work for Petitioner's type of hearing loss, he currently uses a BAHA. Tr. at 12. He developed a pressure ulcer or bedsore due to the BAHA Attract[14] and had to change to a "Connect"[15] device. *Id.* at 13. Petitioner filed a workers compensation claim due to his hearing loss and vertigo, which was denied as it was not a covered problem, and he did not file an appeal. *Id.* at 21.

Petitioner is now deaf on the left side and continues to experience vertigo if he turns quickly or closes his eyes. Tr. at 14–15. Other than some age-related hearing loss, his right ear is normal and he is in normal health. *Id.* at 19. He was initially getting an MRI every six months, but reduced the frequency to once a year, and is planning to reduce it again to once every two years because there is no growth of his tumor noted on the MRI. *Id*. at 15, 21. He also visits his hearing specialist treaters, and undergoes and audiology exam, once a year. *Id*. at 15.

M.R. testified that he has had some difficulties and concerns in daily life due to his hearing loss. He does not have sound localization due to the lack of stereo hearing, but has learned to accommodate this. Tr. at 16. Even with the BAHA, Petitioner can only receive 50 percent of sound on his left side which makes him more cautious while driving. *Id.* at 17. In a professional setting, he must position himself with his right ear toward whoever he is having a conversation with—especially while performing a procedure with a physician, and there is some difficulty when using a stethoscope. *Id*. Petitioner can no longer scuba dive, and he finds it difficult to hear in noisy environment, which has impacted his social life. *Id*. at 18. He has concerns for the future as his insurance does not cover the cost of replacing the BAHA (approximately $5,000) and they tend to wear out every four to five years. *Id.* at 18–19. Petitioner is looking into getting a cochlear implant. *Id*. at 19–20.

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[13] Petitioner described the hyperbaric oxygen therapy as a 60–90-minute session where he was in a pressurized container brought down to two atmospheres at 100 percent oxygen, and slowly brought back up. Tr. at 11.

[14] Petitioner described the Attract as a small screw placed into the mastoid bone behind the ear attached by a magnet. Tr. at 13. The device would attach to the outside of the magnet and the sound was transmitted from the device into the bone, and is picked up by the right ear. *Id.* Petitioner wore this device about 16 hours a day, and the constant pressure of the magnet caused the pressure ulcer or bedsore. *Id.*

[15] The Connect does not use a magnet, but has an abutment post that protrudes through the skin where the device connects. Tr. at 13. Petitioner did not originally opt for the Connect because the skin was not totally closed, and in his role as a registered nurse he has patients with infections, but later determined the risk was low. *Id.* at 14, 22.

B. Petitioner's Expert – Edwin Monsell, M.D., Ph.D.

Dr. Monsell, an otolaryngologist, submitted two expert reports and testified for the Petitioner in support of the contention that the flu vaccine can cause SNHL. *See generally* Tr. at 24–104, 151–58; Report, dated Feb. 27, 2017, filed as Ex. 22 (ECF No. 24-1) ("Monsell First Rep."); Report, dated Jan. 21, 2022, filed as Ex. 24 (ECF No. 70-1) ("Monsell Second Rep.").

Dr. Monsell attended Williams College for his undergraduate degree in biology. *See* Curriculum Vitae, dated Feb. 27, 2017, filed as Ex. 23 (ECF No. 24-2) ("Monsell CV") at 1; Tr. at 24. He also attended Duke University for his doctorate in cell biology and neuroscience, and the University of North Carolina School of Medicine for his medical degree. Monsell CV at 1; Tr. at 24, 32–33. For over 20 years, Dr. Monsell has served as a Director and Professor Emeritus of Otolaryngology—Head and Neck Surgery at Wayne State University. Monsell CV at 1; Monsell First Rep. at 1; Tr. at 27. He has maintained an active practice in otology and neurology for over 30 years, treated thousands of patients with hearing loss, and performed over 3,500 major ear operations to remove tumors, infection, and restore hearing. Monsell First Rep. at 1; Tr. at 107, 110. He is board certified in otolaryngology and neurotology. Monsell First Rep. at 1; Monsell CV at 4; Tr. at 26. He has also published literature specifically on vestibular schwannoma and has around 85 peer-reviewed papers, case reports, and book chapters. Tr. at 30.

Dr. Monsell began by conducting a summary review of Petitioner's medical history, reiterating in the process M.R.'s prior testimony. Tr. at 33–35; Monsell First Rep. at 1–2. He then opined on Petitioner's diagnosis, explaining that he had experienced sudden SNHL in the left ear, vertigo, and tinnitus (although the latter symptom was delayed in its onset). Tr. at 35. In embracing this diagnosis, Dr. Monsell relied on the medical records and Petitioner's treating physicians, who consistently diagnosed Petitioner with SNHL. *Id.* at 37. He also assessed the possibility of Petitioner obtaining a cochlear implant and the role of vestibular schwannoma as a cause of hearing loss, maintaining that the prescribing doctor would need to be sure that the cochlear nerve was active and functional. *Id.* at 151–55.

Dr. Monsell described some of the relevant medical concepts bearing on Petitioner's claim. SNHL, he explained, is generally defined as hearing loss that develops over a 72-hour period, with thresholds worsening by 30 decibels or more in three or more contiguous octave intervals. Tr. at 36; Monsell First Rep. at 2. He distinguished SNHL from comparable conditions, such as age-related hearing loss and noise-reducing hearing loss, which tend to develop gradually over a longer timeframe. Tr. at 36. Importantly, Dr. Monsell admitted that the causal sequence in sudden SNHL is not yet known. Monsell Second Rep. at 1.

Dr. Monsell also discussed some of the risk factors for SNHL, deeming a vestibular schwannoma only one of several. Tr. at 62–63, 70–72. Hypertension and severe obesity, for example, are associated with SNHL's occurrence. *Id.* at 71, 84. One study noted that hypertension

was more prevalent in a group of subjects with sudden SNHL, but otherwise no difference was found in the prevalence of personal cardiovascular risk factors (e.g., hypertension, diabetes, hyperlipidemia, or smoking) in 96 patients with sudden SNHL versus 190 age and gender-matched controls. Monsell First Rep. at 5; I. Mosnier et al., *Cardiovascular and Thromboembolic Risk Factors in Idiopathic Sudden Sensorineural Hearing Loss: A Case-Control Study*, Audiology & Neurotology 55, 62–64 (2011), filed as Ex. 22, Tab S (ECF No. 67-9) ("Mosnier"). Dr. Monsell also suggested that the flu vaccine might heighten the risk for individuals already possessing other risk factors, though he noted herein that Petitioner was probably mostly at risk due to his own obesity or hypertension. Tr. at 71, 84.

Dr. Monsell attempted to downplay the likelihood that a vestibular schwannoma could be a causal explanation for SNHL. Tr. at 62–63, 70–72. He defined a vestibular schwannoma to be a tumor of cells growing on the vestibular (or hearing balance) nerve. *Id.* at 63; Monsell First Rep. at 4–5. They are also called acoustic neuromas. Tr. at 91.[16] A vestibular schwannoma can, he admitted, result in *both* a slow/progressive and more rapid hearing loss. *Id.* at 63; Monsell Second Rep. at 4; A. Aslan et al., *Clinical Observations on Coexistence of Sudden Hearing Loss and Vestibular Schwannoma*, 117 Otolaryngology – Head & Neck Surgery 580, 580 (1997), filed as Ex. 24, Tab A (ECF No. 70-2) ("Aslan").[17]

Vestibular schwannomas can exist without symptoms, and thus are sometimes discovered as an incidental finding—such as in the course of trying to determine the etiology of a patient's headaches. Tr. at 65. Dr. Monsell agreed, however (contrary to his prior contention that acoustic neuromas were not always themselves causal of hearing loss), that the possibility of an acoustic neuroma should be considered in all patients *first* presenting with asymmetric SNHL or with other persistent unilateral or asymmetric ear symptoms. *Id.* at 91. Treatment includes steroids administered intratympanic or orally, and hyperbaric oxygen. *Id.* at 69–70; Monsell First Rep. at 5. Dr. Monsell noted that medical science could at this point only speculate about how an acoustic neuroma might manifest and in turn cause SNHL. Tr. at 65. He also did not deny that there is a statistical and probably causal relationship between sudden SNHL and the discovery of an existing vestibular schwannoma in a relevant individual. *Id.* at 91–92; Monsell Second Rep. at 3.

During his testimony, Dr. Monsell went into great detail as to how the ear works, relying on a diagram to do so. Tr. at 37–42; Trial Ex. 1. He discussed the cochlea—the inner ear—and explained how its many functions are connected. Tr. at 38. The neural tissues of the inner ear are encased in hard bone. *Id.* The cochlea of the inner ear is coiled up, and the area across the spiral is the basilar membrane, which vibrates with the frequency of sound. *Id.* at 39. The hair cells are the auditory receptors, which convert vibrations of sound into nerve impulses. *Id*. These hair cells then bend and mechanically open ion gates, letting in calcium and potassium. *Id.* at 40. There are two

[16] Both terms shall be used interchangeably in this Decision.

[17] Also filed as Respondent's Ex. A, Tab 7. (ECF No. 29-8).

chambers that contain high potassium solution, called the scala vestibuli perilymph and scala tympani perilymph. *Id.* at 38. Additionally, the scala media has endolymph, which is also high in potassium. *Id.* The difference between these chambers is created and maintained by the stria vascularis, which has many blood vessels to provide necessary oxygen and nutrients (and is where the immune-mediating processes have been localized with immunohistochemistry). *Id.* at 38–39, 42. The opening of the ion gates leads to an electrical change in the hair cells, which is picked up at the bottom of the hair cell by the dendrites of the auditory neurons through the synaptic connection. *Id.* at 40.

Dr. Monsell also described the interplay between the inner ear and inflammation. The cochlea is metabolically active, with different structural cells responsible for shunting potassium. Tr. at 42–43; Monsell First Rep. at 5; D. R. Trune, *Ion Homeostasis and Inner Ear Disease*, Medical Otology and Neurotology 21, 24 (2006), filed as Ex. 22 Tab, FF (ECF No. 69-2) ("Trune") (showing the path of potassium recycling). Any form of labyrinthitis (inner ear inflammation) could compromise the ion hemostasis, which is crucial for the function of hearing, by effects on the vasculature of the cochlear lateral wall and stria vascularis. Tr. at 42; Monsell First Rep. at 5; Monsell Second Rep. at 4; Trune at 21. This can often affect the balance function of the inner ear as well. Tr. at 42. However, the inner ear has its own local system for dealing with inflammation. *Id.* at 43–44; M. Fujioka et al., *Inflammatory and Immune Responses in The Cochlea: Potential Therapeutic Targets for Sensorineural Hearing Loss*, 5 Frontiers Pharmacology 1, 1–3 (2014), filed as Ex. 2, Tab J (ECF No. 66-10) ("Fujioka"). For example, macrophages, which are immune surveillance cells, wind their processes through the hair cells and the spiral ligaments and constantly monitor the inner ear for inflammation. Tr. at 43–44; Fujioka at 3.

Next, Dr. Monsell proposed a causal mechanism for sudden SNHL: the stress response theory. Tr. at 45. At the outset, he noted difficulty in studying the inner ear, which made it hard to provide more definitive reliable support for the theory, and there was otherwise no solid proof that this mechanism explains hearing loss, but that the concept had been considered by the scientific/medical community. *Id.* at 45, 50–51, 73, 83; M. Masuda & J. Kanzaki, *Cause of Idiopathic Sudden Sensorineural Hearing Loss: The Stress Response Theory*, 3 World J. Otorhinolaryngology 42, 50 (2013), filed as Ex. 29 (ECF No. 53-1) ("Masuda") (review article discussing potential immune reactant as a stimulation, but not addressing the flu vaccine specifically nor acoustic neuromas); S. Merchant et al., *Pathology and Pathophysiology of Idiopathic Sudden Sensorineural Hearing Loss*, 26 Otology & Neurotology 151, 158–59 (2005), filed as Ex. 24, Tab G (ECF No. 70-8) ("Merchant").

Dr. Monsell deemed Merchant to provide particularly good support for how the stress response theory could explain vaccine-induced SNHL. Tr. at 45–46. Merchant's authors engaged in a postmortem evaluation of human temporal bones in the ear, and they did not conclude that viral infection alone could be causal of sudden SNHL. *Id.* at 46; Merchant at 158–59. However,

Merchant hypothesized that sudden SNHL was most likely the result of activation of cell stress pathways involving the nuclear factor kappa beta ("NF-kB"), the master immune complex that regulates inflammation and responds to injury in the tissue. Tr. at 46, 82; Monsell First Rep. at 5; *but see* Merchant at 158 (none of the studied patients had acoustic neuromas).

Merchant specifically speculated that sudden SNHL might reflect the end-result of rapid progression of events after NF-kB activation. Tr. at 47; Monsell Second Rep. at 1; Merchant at 158–59. SNHL's unilateral character was echoed by animal studies demonstrating that NF-kB was also activated mainly in one ear. Tr. at 47; Monsell Second Rep. at 1; Merchant at 158–59. One animal study (which localized messenger RNA for several inflammatory factors)[18] provided more details about how the NF-kB activation might occur. Tr. at 48; Monsell Second Rep. at 1; J. Adams, *Clinical Implications of Inflammatory Cytokines in the Cochlea: A Technical Note*, 23 Otology & Neurotology 316, 317–20 (2002), filed as Ex. 24, Tab B (ECF No. 70-3) ("Adams"). Adams proposed that a number of hearing issues, including SNHL, might be explained by the disruption of the normal balance of inflammatory cytokines in the ear (through stress stimulation of the NF-kB complex), and thus that a systemic challenge elsewhere in the body could theoretically stimulate the inner ear immune system (though Adams's authors admitted that, given the sparse experimental evidence to support this contention, conclusions about the "possible significance in cochlear pathologies" of NF-kB stimulation were speculative).[19] Tr. at 49–50, 81–82; Monsell Second Rep. at 1; Adams at 321; J. C. Adams et al., *Selective Activation of Nuclear Factor Kappa B in the Cochlea by Sensory And Inflammatory Stress*, Neuroscience 530, 536 (2009), filed as Ex. 24, Tab C (ECF No. 77-1) ("Adams & Seed").

Dr. Monsell then attempted to demonstrate how the flu vaccine in particular could, via the stress response theory, cause SNHL in an individual.[20] Tr. at 51–53; Monsell Second Rep. at 1; *see generally* Adams & Seed at 536–38 (describing how this mechanism works in an animal model). Administration of the vaccine would, he proposed, cause an increase in circulating

[18] Dr. Monsell also mentioned IL-6, one of the key cytokines produced by the activation of NF-kB, and that has the ability to create positive feedback so it can be released by NF-kB and then in turn stimulate NF-kB. Tr. at 51.

[19] On cross examination, Dr. Monsell also addressed articles he cited regarding flu virus proteins allegedly shown to stimulate NF-kB in the immune system. Tr. at 80–81. He admitted that these articles all focused on wild flu virus *infections*, as opposed to a vaccine, and acknowledged that infection and vaccination are different, but argued that what was known about the wild infectious process could still be used as a model. *Id.*

[20] Dr. Monsell denied that variability in immune responses in individuals impacted the validity of his proposed stress response mechanism. Tr. at 58–59; C. Thomas & M. Moridani, *Interindividual Variations in the Efficacy and Toxicity of Vaccines*, Toxicology 204, 207, 209 (2010), filed as Ex. 22, Tab EE (ECF No. 69-1) (offering the hypothesis that adverse reactions may not be random but partly genetically determined, so no two individuals will respond in the exact same way). Additionally, Dr. Monsell addressed anatomical asymmetry, pre-existing cochlear injury, and genetic factors, with one study observing that various forms of stress, challenges, and dysregulation could impact cochlear ischemia and increase cytokine production. Tr. at 59–60; Masuda at 49–50. However, he could not point to evidence of genetic susceptibility for Petitioner to adverse events from vaccination. Tr. at 86–87.

cytokines of several kinds, including IL-6 and interleukin-6. Tr. at 52. In support, Dr. Monsell referenced an article that describes the inflammatory response after flu vaccination, and the kinds of humoral cells that the vaccine can cause to be released or increased. *See, e.g.*, *Id.* at 52, 102–04; Monsell First Rep. at 5; C. Carty et al., *Inflammatory Response After Influenza Vaccination in Men with and Without Carotid Artery Disease*, Arteriosclerosis, Thrombosis, & Vascular Biology 2738, 2741–43 (2006), filed as Ex. 30 (ECF No. 53-2) ("Carty"); P. Liuba et al., *Residual Adverse Changes in Arterial Endothelial Function and LDL Oxidation After Mild Systemic Inflammation Induced by Influenza Vaccination*, Annals Med. 392, 397–98 (2007), filed as Ex. 22, Tab Q (ECF No. 67-7) ("Liuba") (demonstrating inflammation following the administration of the flu vaccine in humans, but noting that the relatively low number of individuals in the study and short duration of follow-up preclude definitive conclusions regarding the significance of their findings). Despite its admitted limitations, Liuba showed (in Dr. Monsell's estimation) that the flu vaccine can result in a mild, measurable, acute phase reaction. Tr. at 52. And Carty revealed how the flu vaccine causes an immediate increase in IL-6—a cytokine known to stimulate NF-kB. *Id.* at 52; Carty at 2739–41. Carty thus allowed for the possibility of NF-kB stimulation in the ear, as well—even if Carty literally *did not discuss* hearing loss as a product of such immune stimulation. Tr. at 78–80.

Liuba and Carty are even less supportive of Dr. Monsell's theory when evaluated more closely. Liuba, for example, involves a distinguishable context—the impact of the inflammatory stimulus of a flu vaccine on arterial endothelial function, as opposed to the inner ear. Liuba at 392. Moreover, Liuba's authors frankly acknowledge that even though they did ascertain some adverse changes in the initial weeks after the "mild systemic inflammation" caused by vaccination, their observations amounted to an unconfirmed hypothesis—especially since the study involved only eight subjects in total. *Id.* at 395, 398. Carty also involves the impact the flu vaccine has in the context of vascular disease, as opposed to a hearing loss condition. Carty at 2738. Moreover, inflammatory markers measured post-vaccination (in the "acute phase response"—close to vaccination, and when the NF-kB pathway would be most active) were generally more elevated in subjects with severe carotid artery disease than those without. *Id.* at 2738, 2741–42. It did not conclude that vaccination could spark vascular disease, or even worsen it amongst those already so diagnosed.

In addition to seeking to bulwark his mechanistic theory, Dr. Monsell attempted to respond to certain items of epidemiologic literature—specifically a study (also offered by Respondent) which had found no association between the flu vaccine and high rates of sudden SNHL. Tr. at 56, 76; R. Baxter et al., *Sudden-Onset Sensorineural Hearing Loss After Immunization: A Case-Centered Analysis*, 115 Otolaryngology – Head & Neck Surgery 81, 84–85 (2016), filed as Ex. 22, Tab B (ECF No. 66-2) ("Baxter").[21] Baxter's authors specifically sought to evaluate the risk of sudden sensorineural hearing loss after the receipt of a large number of commonly-administered

[21] Also filed as Respondent's Ex. A, Tab 8. (ECF No. 29-9).

vaccines—including the flu vaccine. Baxter at 82–83. Utilizing a case-centered method deemed equivalent to a case control study,[22] Baxter considered vaccines administered to members of Kaiser Permanente[23] in Northern California over a six-year period (2007-13), including more than eight million doses of trivalent flu vaccine.[24] *Id.* at 83. Baxter concluded there was no greater risk for hearing loss in the studied subset of patients who received the flu vaccine when compared to background rates. *Id.*

Dr. Monsell challenged Baxter's methodologic reliability. For example, he pointed to its Table 2, which identified a risk interval of 1 to 14 days with an odds ratio of 1.235. Tr. at 56; Baxter at 84. This dataset reveled 92 cases of hearing loss occurring within the observed 14-day risk interval, and when Baxter's authors compared the two groups (vaccinated versus unvaccinated), the odds ratio did not favor an association. Tr. at 56. Dr. Monsell maintained, however, that the standard statistical criterion for significance is a "P value"[25] less than 0.05, so the odds ratio in this case did not permit high confidence in the findings (even if they did not facially favor an association). *Id.* at 56–57. Thus, despite Baxter's overall conclusion, Dr. Monsell denied that it excluded any vaccine association. *Id.* at 58. On cross examination, however, Respondent noted that M.R.'s onset had actually occurred within a *shorter* risk interval also looked at in Baxter (1-7 days), and that Baxter not only evaluated an odds ratio for this period as well but (unlike the expanded 1-14 day period) *did* find a statistically-significant lack of association for the shorter timeframe—a point Dr. Monsell did not persuasively rebut. *Id.* at 76–77; Baxter at 84.

Dr. Monsell also questioned whether Baxter was sufficiently powered to yield reliable results. Tr. at 77; Monsell Second Rep. at 2. However, on cross examination it was pointed out that Baxter's power was actually reflected by the large number of vaccines administered that were then considered in the study. Tr. at 77–78; Baxter at 85. Even though Baxter's authors forthrightly concluded that their findings of a lack of vaccine association were quite robust, given the *eight million flu vaccine doses considered*, Dr. Monsell maintained that the possibility that the flu vaccine could cause sudden SNHL could still not be excluded, even in such a large sample. Tr. at 78; Baxter at 85; Monsell First Rep. at 3–4; Monsell Second Rep. at 2.

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[22] A case-control study is a retrospective "longitudinal epidemiologic study in which participating individuals are classified as either having (cases) or lacking (controls) some outcome and their histories are examined for the presence of specific factors possibly associated with that outcome." Retrospective Study, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=109047 (last visited June 30, 2023).

[23] Kaiser Permanente is a non-profit, health care organization that provides integrated health treatment services to its members.

[24] Petitioner also received the trivalent flu vaccine.

[25] The P value is defined as "the probability of obtaining by chance a result at least as extreme as that observed, even when the null hypothesis is true and no real difference exists; when $P \leq 0.05$ the sample results are usually deemed significant at a statistically important level and the null hypothesis rejected." *P value,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=116692 (last visited June 30, 2023).

In addition, there was a related deficiency in Dr. Monsell's opinion—since much of the literature he relied upon to show vaccination was associated with SNHL involved wholly distinguishable vaccines, rather than the inactivated flu vaccine. Tr. at 73–76; Monsell First Rep. at 2–3; A. Asatryan et al., *Live Attenuated Measles and Mumps Viral Strain-Containing Vaccines And Hearing Loss: Vaccine Adverse Event Reporting System (VAERS), United States. 1990-2003*, Vaccine 1166, 1170–71 (2008), filed as Ex. 22, Tab A (ECF No. 66-1) ("Asatryan")[26] (suggesting that it was biologically possible that hearing loss could be causally associated with the measles and mumps vaccine given that they contain the live-attenuated strains of the viruses (not discussing the inactivated version of the flu vaccine relevant in this case)).

Other studies only addressed the effect of different kinds of wild infections. *See, e.g.*, M. McKenna, *Measles, Mumps, and Sensorineural Hearing Loss*, Annals N.Y. Acad. Sci. 291, 296–97 (1997), filed as Ex. 22, Tab R (ECF No. 67-8) ("McKenna")(studying measles and mumps infections and SNHL); R. Veltri et al., *The Implication of Viruses in Idiopathic Sudden Hearing Loss: Primary Infection or Reactivation of Latent Viruses?*, Otolaryngology – Head & Neck Surgery 137, 140 (1981), filed as Ex. 22, Tab JJ (ECF No. 69-6) (focusing on a theory of reactivation and infectious agents (such as an actual infection as opposed to vaccination)); W. Wilson et al., *Viral and Epidemiologic Studies of Idiopathic Sudden Hearing Loss*, 91 Otolaryngology – Head and Neck Surgery 653, 656 (1983), filed as Ex. 22, Tab LL (ECF No. 69-8) ("Wilson") (centering on viral infections as opposed to vaccination). And some articles involved experiments involving direct stimulation of the ear, as opposed to the systemic impact of vaccination administered elsewhere in the body. L. Davis, *Comparative Experimental Viral Labyrinthitis*, Am. J. Otolaryngology 382, 387 (1990), filed as Ex. 22, Tab G (ECF No. 66-7) (using inner ear or intranasal inoculation in an animal study, which was not how Petitioner received the vaccine in this case).

Ultimately, Dr. Monsell acknowledged that he could not identify *any* paper that specifically addressed the situation of patients with acoustic neuromas who also received the flu vaccine, and whether the two might have any synergistic interaction. Tr. at 98. He also was not aware of medical literature that indicated whether a patient with an acoustic neuroma was more susceptible to sudden SNHL after receiving the flu vaccine. *Id.* at 98.

The vestibular schwannoma that Petitioner was discovered to possess—and which, as Dr. Monsell had acknowledged, was known by medical science to be associated with SNHL—did not alter Dr. Monsell's opinion regarding the vaccine's purported causal role in this case. Tr. at 53–54; Monsell Second Rep. at 2–3. He agreed that literature suggested hearing loss is caused by neuromas like Petitioner's. *See, e.g.*, J. Saunders et al., *Sudden Hearing Loss in Acoustic Neuroma*

[26] Also filed as Respondent's Exhibit A, Tab 10.

Patients, 113 Otolaryngology – Head & Neck Surgery 23, 30–31 (1995), filed as Ex. 24, Tab M (ECF No. 71-4) ("Saunders")[27] (considering what might cause sudden hearing loss in the setting of vestibular schwannoma). Saunders, one of the larger studies specific to the question (albeit now more than 30 years old), evaluated the histories of 13 patients, concluding that it was possible that a vestibular schwannoma may predispose the cochlear system to a biomechanical change, such as a membrane rupture (although no evidence of a membrane rupture was found in its sample). Tr. at 54; Saunders at 30–31. But Saunders also discussed 79 acoustic neuroma patients treated at the author's clinic, all of whom had well-documented sudden SNHL as their initial symptom (ranging from mild to profound). Tr. at 97; Saunders at 26. Although Dr. Monsell admitted that Saunders established the existence of variation for the kind, or causes of, hearing loss in the context of an acoustic neuroma, he argued that rarely can a tumor *alone* be causally associated with SNHL in the absence of other factors, like an inflammatory milieu. Tr. at 97-98; Monsell First Rep. at 5; Monsell Second Rep. at 2–3.

Dr. Monsell thus deemed Petitioner's acoustic neuroma not likely causative of his SNHL. In his view, the nature of Petitioner's SNHL was not consistent with half the cases involving vestibular schwannomas[28] (although this also meant that it was *consistent* with the other half). Tr. at 64, 69–71, 93–94; Monsell Second Rep. at 2–3. Dr. Monsell also alleged that Petitioner's tumor was too small to have caused the severe[29] level of hearing loss present, leaving the flu vaccine as the exclusive cause of Petitioner's injury. Tr. at 64, 69–71, 100. On cross examination, Respondent noted poor scientific or medical correlation between the level of hearing loss and the size of the tumor, but Dr. Monsell maintained that most correlational studies do not measure a tumor as small as Petitioner's, so the studies cannot be applied in the same way (although he could not cite any independent evidence for this contention). *Id.* at 94–96. And in fact, literature offered by Petitioner indicates that small-sized neuromas can cause SNHL. *See, e.g.*, Saunders at 30 (noting variation in size of tumors in studied SNHL patients,).

Petitioner's medical history was, in Dr. Monsell's reading, supportive of the conclusion that the flu vaccine had most likely caused his sudden SNHL. Tr. at 60, 70–72; Monsell First Rep. at 6. Prior to vaccination, M.R. was in excellent general and neurologic health, and had no problems with his hearing or balance prior to vaccination. Tr. at 60–61. Even if Petitioner had

[27] Also filed as Respondent's Ex. A, Tab 5. (ECF No. 29-6).

[28] Inconsistencies with symptoms included Petitioner's presentation of acute vertigo, but Dr. Monsell acknowledged clinical presentations can vary. Tr. at 96–97; Monsell First Rep. at 5. He also agreed that patients with acoustic neuromas sometimes do not find steroid treatments effective (and thus this would not corroborate or rebut the neuroma as causal). Tr. at 97.

[29] The severity was, in Dr. Monsell's view, obvious from Petitioner's medical records—specifically, M.R.'s audiologic findings from an October 30, 2014 visit reporting that the outer hair cells in the left ear had no response. Tr. at 66–67; Ex. 8 at 11. Another visit on November 20, 2014, stated in the audiogram and otoacoustic emissions (another type of auditory test) report that the left ear was not responding at all. Tr. at 65–69; Ex. 8 at 6–7.

already possessed a vestibular schwannoma pre-vaccination, lowering the threshold for cochlear damage, Dr. Monsell could not find evidence of any alternative cause for Petitioner's SNHL other than vaccination. *Id.* at 61, 71.[30] He also represented that the medical record consistently referenced Petitioner's vaccination in relation to his hearing loss (although this contention is not reflective of what the record actually reveals). *Id.* at 61.

Dr. Monsell attempted to diminish the fact that M.R. had received the flu vaccine in several prior years without experiencing any adverse effect. Tr. at 87. It was possible, Dr. Monsell argued, that Petitioner could have been exposed to antigens throughout but that he only reacted after the "last" dose, and there was the inherent variability of immune responses due to age and environmental factors to take into account as well. *Id.* at 87, 101; Ex. 12 at 15. Thus, Dr. Monsell maintained that the stress response theory was still applicable despite the lack of adverse effects after previous vaccinations. Tr. at 87. However, Dr. Monsell acknowledged that aside from a local reaction, the record revealed no evidence of any objective markers of inflammation around the time of hearing loss onset. *Id.*; Monsell Second Rep. at 1. Petitioner also did not undergo the type of testing that would demonstrate inflammation. Tr. at 87–88. And though Dr. Monsell argued that inflammation could be potentially inhibited by steroids (and thus theoretically receipt of steroids could mask an inflammatory background), Petitioner in this case did not even see therapeutic benefit from the steroid treatments he received (something Dr. Monsell argued was simply further proof of the severity of his injury). *Id.* at 88–89.

Finally, Dr. Monsell opined that Petitioner's onset of symptoms (four days after vaccination) was a medically appropriate timeframe in which the proposed inflammatory mechanism would occur. Tr. at 71. Hearing loss symptoms could, under Dr. Monsell's theory, occur as early as one day after trigger, but typically would take a few days to manifest, and could happen even a few weeks afterward. *Id.* at 71–72. In support of this assertion, he referenced Baxter, which had observed 92 cases of hearing loss within the first 14 days of vaccination, and three occurring within a week. *Id.* at 72; Monsell First Rep. at 6; Baxter at 84. He also cited to Carty, which showed vaccine stimulation of IL-6 upregulation still strong at 24-hours post-vaccination, indicating these processes are cascades and there is variability within the ranges discussed. Tr. at 72; Carty at 2741–42.

[30] For example, the medical record established that Petitioner's medical providers had recommended an MRI—the gold standard of diagnostic test for an acoustic neuroma. Tr. 91, 93. When Petitioner first presented to the ER on October 27, 2014, the attending physician noted that potential diagnosis included a CPA tumor (a type of acoustic neuroma). *Id.* at 93; Ex. 7 at 113–15. However, Petitioner's treatment course did not change as a result of his MRI, and there were no additional treatments recommended, even after the MRI revealed the vestibular schwannoma. Tr. at 100.

C. Respondent's Expert – Douglas Bigelow, M.D.

Dr. Bigelow, an otolaryngologist, testified on behalf of Respondent, and submitted two expert reports. *See generally* Tr. at 106–51; Report, dated May 17, 2017, filed as Ex. A (ECF No. 29-1) ("Bigelow First Rep."); Report, dated Sept. 14, 2017, filed as Ex. C (ECF No. 34-1) ("Bigelow Second Rep."). Dr. Bigelow disputed the flu vaccine's role in causing hearing loss.

Dr. Bigelow attended Hamline University for his undergraduate degree in chemistry. *See* Curriculum Vitae, dated May 18, 2017, filed as Ex. B (ECF No. 30-3) ("Bigelow CV") at 1. He then attended the University of Minnesota School of Medicine for his medical degree. Bigelow CV at 1; Tr. at 106. He is currently an Associate Professor in the Department of Otorhinolaryngology: Head and Neck Surgery at the University of Pennsylvania School of Medicine and the Director of the Division of Otology and Neurotology at the University of Pennsylvania Medical Center. Bigelow CV at 2; Tr. at 107. He has over 25 years of experience as an attending physician managing patients with otology problems, including hearing loss, dizziness, and acoustic neuromas. Bigelow First Rep. at 11. He has lectured extensively on hearing loss, dizziness, and acoustic neuromas, and has co-authored at least forty peer-reviewed publications. Bigelow CV at 5–18; Tr. at 108–09. He is also board certified in otolaryngology and neurotology. Bigelow CV at 2; Bigelow First Rep. at 11; Tr. at 107.

Dr. Bigelow began with a background explanation of sudden SNHL. Tr. at 110–14. SNHL typically presents as sudden or rapid hearing loss occurring over a number of hours to a period of days, with some patients also experiencing dizziness. *Id.* at 110–11. Dr. Bigelow stated that an inciting event cannot usually be identified, though some patients have been known to have experienced upper respiratory symptoms beforehand. *Id.* at 111; Bigelow First Rep. at 10. SNHL is, in Dr. Bigelow's view, somewhat common; a 2013 study, for example, determined there are over 66,000 new cases in the U.S. every year. Tr. at 111; Bigelow First Rep. at 8; T. Alexander & J. Harris, *Incidence of Sudden Sensorineural Hearing Loss*, Otology & Neurotology 1586, 1587–88 (2013), filed as Ex. A, Tab 1 (ECF No. 29-2) ("Alexander & Harris").

Though there is no particular demographic of people most prone to SNHL, it occurs more frequently in older patients. Tr. at 112; Bigelow First Rep. at 8; Alexander & Harris at 1588 (noting that 70 per 100,000 patients over 65 experienced sudden hearing loss, whereas approximately 27 per 100,000 patients under 65 experienced the phenomenon). For the majority of SNHL patients, no etiology is ever identified. Tr. at 126; Bigelow First Rep. at 8. Sudden hearing loss is typically diagnosed by an audiogram, and other tests may be ordered, like blood work or an MRI scan to evaluate for the presence of an acoustic neuroma or other tumors. Tr. at 112–13. Treatment focuses on steroids, and occasionally patients also use hyperbaric oxygen. *Id.* at 113. Patients typically have total or partial improvement after steroids, but that is not always the case. *Id.*

Dr. Bigelow next described acoustic neuromas, deeming them an accepted cause of sudden hearing loss. Tr. at 118–19, 121–22, 130; Bigelow First Rep. at 8; Bigelow Second Rep. at 5. While he acknowledged that acoustic neuromas were not *themselves* common, he did not agree with Dr. Monsell's characterization that they were exceedingly rare (and in any event, the point was irrelevant—since it cannot be disputed that *Petitioner* had in this case experienced one). Tr. at 131, 132; Bigelow First Rep. at 9.

A neuroma is a benign tumor growing from the Schwann cells.[31] Tr. at 118. Typically, they occur in the vestibular portion of the eighth cranial nerve, which controls hearing and balance. *Id.* at 118–19. The tumor can grow slowly over a period of years as evidenced by monitoring serial scans. *Id.* at 119. Dr. Bigelow also noted that an acoustic neuroma does not require a triggering factor, such as inflammation, to cause hearing loss, and it is otherwise unknown why, or precisely how, the neuroma precipitates such loss. *Id.* at 132, 135, 144–45; Bigelow Second Rep. at 5. (However, a number of articles filed in this case—including items offered by Petitioner—speculate as to several possible mechanistic explanations. *See, e.g.*, Saunders at 30 (considering whether neuromas cause hearing loss due to "occlusion of the internal auditory artery," "conduction block of the cochlear nerve action potential," tumor size, tumor growth rate, or by predisposing "the cochlear system to biomechanical change" or "to an inflammatory process"); E. Sauvaget et al., *Sudden Sensorineural Hearing Loss as a Revealing Symptom of Vestibular Schwannoma*, Acta Oto-Laryngological 592, 594 (2005), filed as Ex. C, Tab 5 (ECF No. 34-6) ("Sauvaget") (listing four possible mechanisms for SNHL, and deeming only one (endolymphatic hydrops—also known as Menieré's disease) unlikely)).

The classic clinical presentation associated with the existence of an acoustic neuroma is progressive hearing loss that is associated with vertigo and ringing noises, pressure, and fullness in the affected ear. Tr. at 121, 145. Some individuals with a neuroma never experience hearing loss at all. But Dr. Bigelow opined that anywhere from 3-20 percent of acoustic neuroma patients experience *sudden* hearing loss, making them at high risk for SNHL. Tr. at 130–31, 134, and 145–46; Bigelow First Rep. at 9; Bigelow Second Rep. at 5, 8; D. Moffat et al., *Sudden Deafness in Vestibular Schwannoma*, J. Laryngology & Otology 116, 117 (1994), filed as Ex. C, Tab 1 (ECF No. 34-2) ("Moffat") (identifying a 12 percent incidence of sudden SNHL in 284 patients with vestibular schwannomas; in 10 percent of patients, sudden SNHL was the presenting symptom for the undiscovered neuroma); H. Berg et al., *Acoustic Neuroma Presenting as Sudden Hearing Loss with Recovery*, 94 Otolaryngology – Head & Neck Surgery 15, 17 (1986), filed as Ex. C, Tab 3 (ECF No. 34-4) (detecting a 13 percent incidence of sudden SNHL in 133 patients with acoustic

[31] Schwann cells are "any of the large nucleated cells whose cell membrane spirally enwraps the axons of myelinated peripheral neurons and is the source of myelin; a single Schwann cell supplies the myelin sheath between two nodes of Ranvier." *Schwann Cell,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=64407&searchterm=Schwann+cell (last visited June 30, 2023).

neuromas); M. Pensak et al., *Sudden Hearing Loss and Cerebellopontine Angle Tumors*, Laryngoscope 1188, 1188 (1985), filed as Ex. C, Tab 4 (ECF No. 34-5) ("Pensak") (pinpointing a 14.5 percent incidence of sudden SNHL in 69 patients with acoustic neuroma); Sauvaget at 593 (finding a 20 percent incidence of sudden SNHL in 139 patients with vestibular schwannomas). Dr. Bigelow noted that treatment for acoustic neuroma patients with hearing loss can include steroids, although they are not consistently effective. *Id.* at 124; Bigelow First Rep. at 11.

In addition, Dr. Bigelow stressed that acoustic neuromas can cause profound hearing loss regardless of the tumor size. Tr. at 124, 132. Dr. Bigelow noted that in his practice and in the literature, it was also fairly common for a patient to have a small tumor and yet experience profound hearing loss. *Id.* at 122–24; Bigelow First Rep. at 8–9; K-H. Jeong et al., *Abnormal Magnetic Resonance Imaging Findings in Patients with Sudden Sensorineural Hearing Loss*, 95 Medicine 1, 3 (2016), filed as Ex. A, Tab 2 (ECF No. 29-3) ("Jeong") (recognizing that sudden SNHL is more frequently encountered in small tumors less than 1 centimeter (as is the case herein) than in medium-sized tumors greater than 1 centimeter); C. Lin et al., *The Clinical Characteristics and Treatment for Sudden Sensorineural Hearing Loss with Vestibular Schwannoma* Eur. Archives Otorhinolaryngology 839, 841–42 (2015), filed as Ex. A, Tab 3 (ECF No. 29-4) ("Lin") (discussing how small tumors more easily cause sudden SNHL than larger tumors); Aslan at 581–82 (finding that sudden hearing loss is less frequently seen in larger tumors and there was no obvious frequency difference in cases with small tumors and medium tumors). Petitioner's tumor was 5 millimeters (half a centimeter) in size, and thus consistent with the observations of articles like Lin or Jeong. Tr. at 123; Ex. 5 at 58.

Dr. Bigelow then summarized M.R.'s medical history. Tr. at 114–21. He noted Petitioner's first visit to a medical provider following his flu vaccination on October 27, 2016. *Id.* at 114; Ex. 7 at 113–15. The record from this ER visit reflected that Petitioner had experienced abrupt onset of painless vertigo beginning two days prior that turned into more constant symptoms on the day of presentation. Tr. at 114; Ex. 7 at 113–15. Petitioner's examination produced results deemed within normal limits, except for some horizontal nystagmus. Tr. at 114; Ex. 7 at 113–15. The differential diagnoses include CPA tumor (also known as an acoustic neuroma). Tr. at 114–15; Bigelow First Rep. at 8; Ex. 7 at 113–15. This was the space between the cerebellum pons and the temporal bone—an area where the seventh and eighth nerves travel from the brainstem to get into the internal auditory canal. Tr. at 114. Petitioner also had a CT scan during this visit, which came back negative, but Dr. Bigelow explained that it was often difficult to see an acoustic neuroma via this kind of imaging. Tr at 115; Ex. 7 at 113–15.

After this ER visit, Petitioner saw Dr. Goldrich on October 30, 2014. and the examination was unremarkable except findings suggesting hearing loss in the left ear. Tr. at 115–16; Ex. 5 at 43–46. An audiogram was also performed on that date confirming profound SNHL on the left side. Tr. at 116; Bigelow First Rep. at 7; Ex. 5 at 54–55. The audiologist's impression was consistent

with the examination, and there was an addendum added by Dr. Goldrich diagnosing Petitioner with left-sided SNHL. Tr. at 116–17; Ex. 5 at 55. On November 3, 2014, Petitioner saw Dr. Kwartler, who continued with treatment and scheduled an MRI, which Dr. Bigelow argued was intended to rule out acoustic neuroma or another type of tumor. Tr. at 118–19; Ex. 9 at 18. But the noncontrast MRI scan[32] revealed a round 5-milimeter structure in the left internal auditory canal, which most likely represented a vestibular schwannoma, and further MRI scans were recommended. Tr. at 120; Bigelow First Rep. at 7; Ex. 5 at 58. A later MRI from July 2021 noted the presence of a stable left-sided vestibular schwannoma. Tr. at 120–21; Ex. 31 at 12–13. The scan suggested that the tumor had not grown from the time of diagnosis. Tr. at 121; Ex. 31 at 12–13.

At the time of this hearing, Petitioner was considering a cochlear implant, which Dr. Bigelow agreed was reasonable if the hearing loss was centered in the cochlea. Tr. at 133–34, 148–49. However, he did not agree that this suggested the vestibular schwannoma had not likely caused Petitioner's sudden SNHL. *Id.* at 134. Cochlear implants used by patients with acoustic neuromas have variable results, and are in Dr. Bigelow's experience often utilized even though the cochlea is *not* the most likely source of the SNHL. When an acoustic neuroma causes an issue with the cochlear labyrinthine artery that supplies blood to the cochlea, then the cochlear nerve may be functioning, and a cochlear implant will provide a benefit. *Id.* at 149–50. However, if the cochlear nerve is damaged such that it cannot transmit electrical signals from the cochlea, then the cochlear implant will not provide a benefit. *Id.*

On cross examination, Dr. Bigelow was asked questions about whether Petitioner's clinical presentation and testing results were consistent with a neuroma as causal. He was confronted with the fact that Saunders suggested that vestibular symptoms were not usually present in SNHL patients with acoustic neuroma. Tr. at 146–47; Bigelow First Rep. at 8–9; Saunders at 30. But Dr. Bigelow argued in response that it is understood that vestibular symptoms *can* be present with an acoustic neuroma. Tr. at 146; Bigelow Second Rep. at 5–6. He also disputed Saunders's proposition that an acoustic neuroma would predispose the cochlear system to an inflammatory process capable of harming hearing (thus suggesting the vaccine could interact with such a process). Tr. at 147; Bigelow First Rep. at 8–9; Saunders at 8.

Dr. Bigelow did not find Dr. Monsell's theory of causation reliable, although he credited many of Dr. Monsell's foundational points about the different possible means by which the ear's functioning can be compromised.[33] Tr. at 127–29, 138; Bigelow First Rep. at 10. Masuda, which

[32] Dr. Bigelow explained that the noncontrast scan would not affect the results, but giving contrast (or gadolinium) provides more information, as acoustic neuromas will typically "light up" in the image produced, becoming bright and thus more easily identified. Tr. at 120.

[33] For example, Dr. Bigelow said it was conceivable that inflammation of the inner ear can compromise ion homeostasis. Tr. at 137. He agreed that NF-kB is a transcription factor found throughout the body, with a significant

discussed the stress response theory embraced by Dr. Monsell, was now eight years old, with no subsequent studies corroborating its findings. Tr. at 128–29; Masuda at 42. Otherwise, the concept Masuda embraced was not, in Dr. Bigelow's understanding, widely accepted among the medical community. Tr. at 129. Dr. Bigelow also did not find the research from Merchant on the activation of NF-kB cells applicable. Tr. at 128; Merchant at 158–59. Merchant's authors had artificially induced an inflammatory response by directly injecting lipopolysaccharides into the abdomen of a mouse—hardly equivalent to the impact of a vaccine in a human. Tr. at 128, 138–39, 141–43; Bigelow Second Rep. at 6; Merchant at 159. Otherwise, even if Dr. Monsell's theory was correct, Dr. Bigelow would have expected steroid treatments to reduce inflammation, as reflected in the Adams & Seed study, and thus mitigate any sudden hearing loss. Tr. at 129; Adams & Seed at 537 ("[t]he fact that steroids are potent blockers of NF-kB activation suggests that . . . this activation could be blocked or reversed by steroid treatment"). Yet steroids had not been effective for Petitioner—further undermining the applicability of the stress response theory to this case. Tr. at 129.

Dr. Bigelow admitted that he had not submitted literature directly *disputing* the validity of the stress response theory, but he opined that if the proposed mechanism was significant in causing SNHL, there would be more cases of sudden hearing loss generally, given how common "stress" of all kinds is in daily life. Tr. at 144. He also denied that any literature supported the specific proposition that the flu vaccine causes or is associated with sudden hearing loss.[34] *Id.* at 126; Bigelow First Rep. at 9; Bigelow Second Rep. at 6. To the contrary—some large scale studies undermined the possibility of such an association. Baxter, for example, considered more than eight million vaccination doses, finding there was no correlation between vaccination and sudden hearing loss. Tr. at 126; Bigelow First Rep. at 9; Bigelow Second Rep. at 6–7; Baxter at 85. At most, Dr. Monsell could point to studies associating hearing loss with distinguishable vaccines, like the MMR—but that vaccine contained antigens of a wild virus (mumps) that was *also* associated with hearing loss, *unlike* the wild flu virus. Tr. at 126–27; Bigelow First Rep. at 9–10; Asatryan at 1166, 1168. And Dr. Bigelow deemed public surveillance data connecting the flu vaccine to SNHL to be particularly unreliable, since anyone can report a post-vaccination symptom, regardless of whether the claimed adverse effect actually happened. Tr. at 127.

Dr. Bigelow thus ultimately opined that the flu vaccine had not caused M.R.'s sudden SNHL. Tr. at 133. Though M.R. had testified that after receiving the vaccine he experienced

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amount present in the cochlea. *Id.* at 137–38. He agreed that NF-kB was originally believed to have a protective effect of the inner ear. *Id.* at 138. And he accepted that when NF-kB is pathologically activated, it can operate as a cellular stress pathway that can react to cytokine production. *Id.*

[34] Dr. Bigelow referenced one case report from 2010, which discussed an instance of bilateral sudden deafness following the H1N1 vaccination, but noted that the exact cause had not therein been conclusively identified. Bigelow First Rep. at 9; H-H. Huang et al., *Bilateral Sudden Deafness Following H1N1 Vaccination*, 143 Otolaryngology – Head & Neck Surgery 849, 850 (2010), filed as Ex. A, Tab 9 (ECF No. 29-10). That version of the flu vaccine is not at issue in this case. Bigelow First Rep. at 9.

inflammation at the injection site and pain radiating up to his neck and left ear, Dr. Bigelow argued that this reaction did not likely have any bearing on his sudden hearing loss, since post-vaccination malaise-like reactions were common (and could cause some radiating pain as well). *Id.* at 125. And (contrary to Dr. Monsell's opinion), Dr. Bigelow did not find that any of M.R.'s treating physicians proposed an association with the flu vaccine. *Id.* at 129. Thus, although Dr. Goldrich noted in a medical history section of a record that Petitioner's hearing loss occurred after vaccination, he had provided no professional commentary on whether there was any scientific/medical association between the vaccine and SNHL. *Id.* at 130; Ex. 7 at 25.

However, Dr. Bigelow did not deem the cause of M.R.'s hearing loss to be unknown. Rather, he firmly opined that the most likely cause was his acoustic neuroma, giving its well-understood association with SNHL. Tr. at 130, 132; Bigelow First Rep. at 8, 10–11. Petitioner's vestibular schwannoma likely existed prior to his vaccination but was asymptomatic. Tr. at 135–36.

Dr. Bigelow concluded with a discussion of the timing of Petitioner's onset, denying that the manifestation of M.R.'s vertigo and hearing loss four days after vaccination said anything about the likelihood of causation. Tr. at 125, 147–48; Bigelow First Rep. at 10. In support, he referenced Baxter, noting that it only showed a heightened risk of association in a *longer* timeframe. Tr. at 136; Bigelow First Rep. at 9; Baxter at 84.

III. Overview of Literature

Petitioner filed approximately 52 articles or items of medical literature, compared to the 17 filed by Respondent. Not a single item filed by Petitioner directly supports the contention that the flu vaccine—or even a wild flu viral infection—could cause an immune-mediated stress response sufficient to lead to hearing loss.[35] Rather, Petitioner's filings address discrete aspects of the overall theory, linking them together with argument and the testimony of Dr. Monsell. By contrast, several items of literature cited by Respondent *stand directly for the proposition* that SNHL can *be caused* by an acoustic schwannoma/neuroma.[36] Moffat at 117; Pensak at 1188; Saunders at 26,

[35] Petitioner has filed literature suggesting a link between the MMR vaccine/viruses and hearing loss (*see, e.g.*, McKenna and Asatryan), but this case does not involve that vaccine or the underlying viral antigens it contains.

[36] In making this observation, *I am not requiring Petitioner to offer direct proof of causation.* I am more than well aware that no such requirement is imposed upon Program claimants. Rather, I am merely observing that Petitioner's theory relies on a chain of indirect/circumstantial contentions, whereas Respondent's counter-causation theory has robust *direct* support. This observation is reasonably-made, and bears on my evidentiary weighing; direct evidence that one kind of factor "can cause" an injury is inherently stronger than indirect proof of another. When the Respondent can offer direct proof that rebuts a claimant's theory, made up of a chain of many indirect points, it is reasonable to give greater weight to the Respondent's case—and it is not unfair, or against the policy goals of the Program, to do so.

30–31; Sauvaget at 593. In briefing this matter on remand, neither side filed any additional or more recently-published items of literature relevant to the claim.

IV. Procedural History and Remand Order

M.R. filed his petition on August 18, 2016, but it took nearly five years to complete records filing and expert report input. After the matter was transferred to me in March 2021, I held a status conference with the parties and subsequently scheduled the matter for a February 2022 one-day trial. ECF No. 50. The trial occurred as scheduled. After a review of the record, I issued a decision denying entitlement. *See M.R. v. Sec'y of Health & Hum. Servs.*, No. 16-1024V, 2022 WL 16956497 (Fed. Cl. Spec. Mstr. Oct. 3, 2022).

Petitioner appealed my determination, however, and his Motion for Review was granted on March 27, 2023, resulting in my prior decision being vacated. Remand Order at 1, 12. In particular, the Court has instructed me "to clarify [the] factual findings, use the analytical framework for causation appropriate given those findings, and further develop the record as needed to perform a proper *Shyface* analysis." *Id.* at 12 (*citing Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)). To this end, I have been directed to clarify whether I had found that: "(1) there was no evidence supporting the vaccine as a cause; or (2) evidence supported the vaccine as a cause, but that the acoustic neuroma either (a) 'overwhelmed' the vaccine as a contributing factor; or (b) was the independent cause of Petitioner's injury." *Id.* at 9. To the extent the neuroma and vaccine could have *both* played a role in causation, I am to perform the *Shyface* analysis of whether each potential cause was a but-for cause and a substantial factor of the harm, and carefully weigh the contributing factors in so doing. *Id.* at 10.

I subsequently issued an Order to Show Cause, instructing Petitioner to explain why I "should not again determine that [Petitioner] has not carried his burden of proof, and that the claim should be dismissed." ECF No. 100. The parties have since filed their briefs and the matter is ripe for resolution. *See* Petitioner's Brief, dated May 5, 2023 (No. 101) ("Br."); Respondent's Opposition, dated June 2, 2023 (ECF No. 102) ("Opp.").

IV. Parties' Arguments on Remand

The Remand Order allowed for the possibility of additional record development, if deemed necessary. Remand Order at 9, 11. However, neither party asked for such an opportunity in briefing their positions—nor (as noted above) did they file any additional recently-published literature regarding the issues in dispute that would support reopening the record for additional expert input. Because of this, and because I independently have concluded that the existing record (in a case that is now *seven years old*—meaning the parties were clearly provided ample opportunity to identify and file evidence in support of their positions), is sufficiently complete, I shall decide this matter solely on the existing record plus new briefing.

Petitioner

Petitioner began by emphasizing the undisputed fact that he suffered from left-sided SNHL. Br. at 13.[37] He then provided his characterization of a proper *Shyface* analysis. Br. at 14–29. Where, as here (Petitioner maintains), two possible causes for an injury exists, a claimant need not demonstrate that the vaccine was the *most* substantial contributing factor of the two, but rather is obligated only to establish that it was a likely *a* substantial contributing factor to some degree (albeit in a "but for" sense—meaning that the injury could *not* have occurred without vaccination, even if the proportion of "blame" cannot be determined). *Id.* at 16, n.15; Reply at 4. It is thus not his burden to prove the vaccine "triggered" hearing loss in the context of a pre-existing neuroma, only that the vaccine acted as a factor in that loss. Reply at 4. In so arguing, Petitioner conceded that "an asymptomatic acoustic neuroma is a risk factor for hearing loss," but maintained that Dr. Monsell's causation theory would apply regardless of the role the neuroma played (and thus could explain hearing loss even if the "acoustic neuroma was coincidentally present." *Id.* at 4 n.9.

Here, Petitioner maintains, the record contains enough evidence to support the conclusion that the flu vaccine was just that sort of substantial contributing factor. He notes that the filed medical literature (along with Dr. Monsell's testimony) describes a mechanism—the "stress response theory"—for how the flu vaccine could stimulate an aberrant immune process (mediated by inflammation) resulting in SSNHL. Br. at 21, 25, 39–34; Reply at 4, 6. The flu vaccine could cause sudden hearing loss via this mechanism regardless of whether the neuroma was coincidently present and/or a pre-existing condition that lowered the threshold for the attendant cellular damage. *Id.* at 24, 34–35.

The neuroma, by contrast, might well have had nothing to do with Petitioner's SSNHL. The neuroma likely pre-existed the vaccination, and was thus "asymptomatic" until the hearing loss's manifestation. Br. at 17, 21. Medical literature strongly supports the conclusion that acoustic neuromas in fact often exist incidentally and asymptomatically in the general population. *Id.* at 18–19, 22; Reply at 11. Moreover, even if a neuroma is a known risk factor for developing hearing loss (as both parties' experts agreed), the fact that Petitioner had experienced no hearing loss pre-vaccination was, in Petitioner's estimation, significant. *Id.* at 17, 20, 22–2; Reply at 53. And Petitioner's MRIs consistently show that his acoustic neuroma has remained stable, without

[37] Petitioner contests my use (as well as the Court's) of the shortened acronym "SNHL," maintaining that it is not interchangeable with SSNHL, since there are other types of sensorineural hearing loss that can occur gradually or progressively. Br. at 13. I agree that his hearing loss was indeed "sudden," but note as well that my use of the shortened acronym was intended solely for purposes of brevity. It does not amount to a mischaracterization or misunderstanding of the underlying diagnosis, since it is not disputed at all that Petitioner's hearing loss came on suddenly, and was not progressive or apparent pre-vaccination (even though the likely-causal neuroma surely was present before). In fact, a different acronym entirely—"SSHL" is used in many of the items of literature filed in this case (also standing for "sudden sensorineural hearing loss"). *See, e.g.*, Sauvaget at 592; Baxter at 81.

change, since its discovery in 2014—raising the plausibility of the conclusion that Petitioner would not have developed SSNHL "but for" vaccination. Br. at 25.[38]

Petitioner further identified record support that he proposes bulwarks the likelihood of the vaccine's causative role. Petitioner's clinical presentation, for example, was inconsistent with what is associated for significant vestibular symptoms. His hearing loss was sudden and profound—even though hearing loss due to an acoustic neuroma (as Respondent's expert admitted) tends to progress more gradually. Br. at 20; Reply at 9–10. And the record "documented the development" of Petitioner's SNHL "in the context of his flu vaccination." Br. at 28. Indeed, treaters recommended that Petitioner receive a lifelong exemption from it. *Id.* at 26, 28. In so arguing, Petitioner emphasizes that the Federal Circuit has agreed that evidence of such an exemption can be probative of treater views on causation. *Id.* at 26; *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1376 (Fed. Cir. 2009). Respondent's contention that Petitioner cannot substantiate the fact of this purported exemption is rebutted by Petitioner maintaining his employment in the medical field as a nurse (since he would logically be required to be vaccinated otherwise). Reply at 6–7.

Petitioner also attempts to rebut Respondent's broader contentions about the demonstrated lack of association between the flu vaccine and hearing loss in relevant epidemiologic studies. All the Baxter study establishes (in Petitioner's estimation) is a failure to find a statistically significant association—not that one could *never* exist. Reply at 2–3. Epidemiologic studies simply cannot detect rare events, and in any event petitioners need not offer this kind of evidence to prevail (thus suggesting to Petitioner that it has no bearing on this case at all—a dubious contention, as noted below). Reply at 2–4; *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1325 (Fed. Cir. 2010).

The other causation elements are met in this case. Petitioner reiterates findings from my original decision regarding onset timing, noting that his SSNHL occurred four days post-vaccination—a timeframe "consistent with his theory about how long an aberrant cytokine-driven process would take to occur." Br. at 29, 22; *M.R.*, 2022 WL 16956497, at *21, n.37. This timeframe reflected how long an inflammatory-mediated reaction would be thought to occur, and was supported by Baxter's findings as well. Reply at 7–8.

While arguing that he has carried his evidentiary burden, Petitioner additionally maintained that Respondent had not preponderantly demonstrated that the neuroma was the "factor unrelated"

[38] Petitioner also notes that even when an acoustic neuroma is present, other precipitating events can contribute to the pathology of hearing loss, including but not limited to anatomical asymmetry, pre-existing cochlear injuries, or genetic factors. Reply at 5. But the same is true in *any* vaccine injury case—rare is the Program petitioner who does not maintain that injuries typically occur *in the context* of some petitioner-specific susceptibility, independent of the vaccination—and thus this point does not undermine the evidentiarily-established fact that *neuromas are associated with hearing loss but the flu vaccine is not*.

cause of his SSNHL, while the vaccine was not. In so arguing, Petitioner stressed that even if neuromas are known to be associated with hearing loss, the *mechanism* by which they cause this injury is not, as Dr. Bigelow acknowledged. Br. at 18, 22. Pointing out that the Remand Order took notice of this as well ("[i]t is of some significance to this Court that the Government's expert admitted that science has yet to explain 'the mechanism by which a subclinical acoustic neuroma becomes symptomatic with hearing loss'" (Remand Order at 12)), Petitioner maintains that Respondent has not satisfied his preponderance burden in an alternative cause action. Br. at 37; Reply at 9. Respondent also did not offer evidence establishing a medically acceptable timeframe for neuroma-caused hearing loss. Reply at 10.

Respondent

Respondent argues that Petitioner has not met his causation burden. Opp. at 10. He maintains that Petitioner has not submitted reliable medical literature supporting the conclusion that the flu vaccine can cause SNHL—*regardless* of whether an individual possesses an acoustic neuroma. Opp. at 11–13. As Dr. Bigelow explained, Dr. Monsell essentially pieced together many different items of literature to create an unproven, patchwork theory implicating the flu vaccine, even though he outright conceded that the flu vaccine (as well as the influenza wild virus) is not associated with high rates of SSNHL in epidemiologic studies. *Id.* at 11–12. And although Petitioner noted his causation theory had found acceptance in at least one other recent Program case, Respondent deemed the result therein inapplicable, since (unlike here) the facts of that case presented no clear alternative explanation for the SSNHL at issue—whereas here the neuroma unquestionably exists. Opp. at 13 (referencing *Madigan v. Sec'y of Health & Hum. Servs.*, No. 14-1187V, 2021 WL 3046614, at *17 (Fed. Cl. Spec. Mstr. June 25, 2021) (deeming the stress response theory as explaining how the flu vaccine could cause SNHL "sound and reliable")).

Next, Respondent argues that Petitioner cannot preponderantly establish that the flu vaccine "did cause" his SSNHL. Opp. at 13. Despite insisting on the need for a *Shyface* evaluation of competing (or concurrent) causal factors, Petitioner never explains how, or even whether, the flu vaccine interacted with his acoustic neuroma to cause hearing loss (since if both were causal, they logically should be shown to interact in some fashion). *Id.* at 13–14. Dr. Bigelow, by contrast, persuasively testified that acoustic neuromas can cause hearing loss *by themselves*, without the need for any trigger or co-factor. *Id.* In this regard, the fact that Petitioner had previously received the flu vaccine several times without reaction or incidence was, in Respondent's estimation, significant, since presumably the same circumstances for the vaccine to influence the undiscovered neuroma existed in the past, but without the triggering of hearing loss. *Id.*

Respondent also sought to rebut Petitioner's arguments about treater views as supportive of a vaccine-injury causal association. The medical records reveal that Petitioner's treating physicians merely *mentioned* (in medical history recounts contained in records) that he had

received a flu vaccine prior to onset, but never discussed an association or proposed a causal relationship. Opp. at 15. And Petitioner's supposition that he was granted a lifelong exemption from receiving the flu vaccine is not directly corroborated in his medical or employment records, but instead merely secondarily referenced in statements *he made* to his PCP. *Id.* By contrast, Respondent could point to several record instances in which treaters associated Petitioner's acoustic neuroma with his hearing loss. *Id.* at 16, referencing Ex. 9 at 13–14 (Dr. Kwartler advising petitioner to consider tumor removal and/or monitor neuroma growth); Ex. 26 at 5 (Dr. Kwartler advising continued monitoring); Ex. 21 at 1-2 (Dr. Matlin advising monitoring of the acoustic neuroma in conjunction with annual audiological exams); Ex. 27 at 214 (Dr. Cassidy stating that Petitioner experienced an "acoustic neuroma culminating in the need for a BAHA procedure.").

Finally, Respondent contends that he has proven that the neuroma was a "factor unrelated" cause of Petitioner's injury, with the vaccine excluded as causal. Opp. at 11, 18. Acoustic neuromas are a studied, scientifically-confirmed cause of sudden hearing loss, and the size of Petitioner's acoustic neuroma (which Dr. Monsell maintained at hearing was too small to be causal) is also so associated. *Id.* at 18. In addition, Petitioner's hearing loss only occurred in his left ear—the location of the neuroma. *Id.* Petitioner's treating otolaryngologists or audiologists never attributed his injury to the flu vaccine, whereas the diagnosis of his hearing loss was related to his acoustic neuroma, which was substantiated by recommendations to continue monitoring the tumor and its possible removal. *Id.* at 19. And the fact that the mechanism by which a neuroma can cause hearing loss is unknown (whereas Petitioner has offered a mechanism for how the vaccine could cause injury) is irrelevant; *no one* in the Program (petitioners, or even Respondent in the occasions when he is obligated to carry an alternative cause burden) need prove a specific mechanism to prevail. Ultimately, overwhelming evidence filed in this case establishes that acoustic neuromas do cause hearing loss, compared to Petitioner's showing regarding the flu vaccine. *Id.* at 19–20.

V. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly*, 592 F.3d at 1321; *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[39] In this case, Petitioner does not assert a Table claim.

[39] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface*, 165 F.3d at 1352–53); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu*, 569 F.3d at 1378–79 (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters

concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof" (citing *Moberly*, 592 F.3d at 1322)); *Howard v. Sec'y of Health & Hum. Servs.*, No. 16-1592V, slip op. at *6 (Fed. Cl. Feb. 27, 2023) (confirming that "[t]he standard has been preponderance for nearly four decades"), *appeal docketed*, No. 2023-1816 (Fed. Cir. Apr. 28 2023). Otherwise, petitioners *always* have the ultimate burden of establishing their Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals.

Hibbard v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum.*

Servs., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible

explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

ANALYSIS

I. Treatment of Hearing Loss Claims in the Vaccine Program

Program claimants have frequently argued that SNHL/SSNHL was attributable to a vaccine. More often than not, such claims have not succeeded.[40] *See, e.g.*, *Kelly v. Sec'y of Health & Hum. Servs.,* No. 16-878V, 2021 WL 5276373, at *23 (Fed. Cl. Spec. Mstr. Oct. 18, 2021), *mot. for review den'd*, 2022 WL 2314746 (Fed. Cl. Apr. 13, 2022) (petitioner failed to establish any preexisting condition that was aggravated by the flu vaccine); *Inamdar v. Sec'y of Health & Hum. Servs.*, No. 15-1173V, 2019 WL 1160341, at *16 (Fed. Cl. Spec. Mstr. Feb. 8, 2019) (referencing multiple prior negative decisions involving SNHL or hearing loss); *Donica v. Sec'y of Health and Hum. Servs.*, No. 08-625V, 2010 WL 3735707, at *1, 10 (Fed. Cl. Spec. Mstr. Aug. 31, 2010) (flu vaccine not demonstrated to cause adult hearing loss); *Hopkins v. Sec'y of Health & Hum. Servs.*, Nos. 00-745V & 00-746V, 2007 WL 2454038, at *13 (Fed. Cl. Spec. Mstr. Aug. 10, 2007) (noting that the specific onset of hearing loss in child siblings after receipt of several vaccines could not be established). In most such cases, the *fact* of post-vaccination SNHL was not disputed, but the claimants could not demonstrate the vaccine was causal.

I recently decided entitlement in *Kelly,* a case in which it was similarly alleged that the flu vaccine had caused SSNHL. *Kelly*, 2021 WL 5276373, at *1. Although that petitioner maintained a significant aggravation claim, I found that my determination would have been the same even if the petitioner had alleged a causation-in-fact claim, and a discussion of all three *Althen* prongs was incorporated in that decision. *Id.* at *24. Petitioner proposed two mechanisms, a rapid Type I sensitivity reaction and an autoimmune response. *Id.* at *25. There was limited evidence to support this connection, however, and petitioner's contention that sudden hearing loss could be driven by an autoimmune process was inconsistent with the timeframe presented. *Id.* I also found that the petitioner's onset of less than two hours was too short to be deemed medically acceptable. *Id.* at *24.

In *Inamdar* (another case I decided), a petitioner argued that the flu vaccine had caused SSNHL, with onset the following day, based on two theories. *Inamdar,* 2019 WL1160341, at *5. First, the claimant argued that the vaccine "could cause the production of proinflammatory cytokines immediately upon vaccine administration." *Id.* But I determined that this argument relied too heavily on what was known about the wild virus rather than the vaccine. *Id.* at *6. The second

[40] As noted above, I am not bound by the decisions of my colleagues—or even the Court's relevant decisions on review (except when stemming directly from a case I decided). *Boatmon*, 941 F.3d at 1358–59; *Hanlon*, 40 Fed. Cl. at 630. At the same time, special masters reasonably draw upon their overall, collective experience in resolving Vaccine Act claims. *Doe v. Sec'y of Health & Hum. Servs.*, 76 Fed. Cl. 328, 338–39 (2007) ("[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the expertise and experience to know the type of information that is most probative of a claim"). They would thus be remiss in ignoring prior cases presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions.

theory was that specific components of the vaccine "were structurally homologous with ganglioside receptors on the neuronal myelin contained in the inner ear tissue, and that antibodies generated in response to the vaccine could also cross-react with the self-myelin, resulting in tissue damage." *Id.* I found, however, that this contention misapplied mechanisms relevant in other contexts. I also ruled that an alternative cause for the SSNHL (the fact that the claimant was receiving antibiotics at the time) existed, as well as that the short onset was not preponderantly defended. *Inamdar,* 2019 WL1160341, at *19. A too-short onset has been a notable obstacle to recovery in other cases. *See, e.g.*, *Donica,* 2010 WL 3735707, at *13 (two-hour post-vaccination onset of SNHL not demonstrated to be medically acceptable).

A different recent reasoned decision, by contrast, resulted in an entitlement decision favorable to the petitioner. *See Madigan*, 2021 WL 3046614, at *1, 4 (flu vaccine caused adult petitioner's SNHL). The *Madigan* petitioner relied on the stress response theory (also utilized in this case) and a theory of reactivation of a latent HSV-1 infection (although the latter did not play into the case's resolution), utilizing an expert different from Dr. Monsell. *Madigan,* 2021 WL 3046614, at *9–10, 17. As observed in *Madigan,* the stress response theory had not been presented in prior adverse decisions like *Inamdar* or *Kelly.* The theory as presented therein placed special emphasis on the NF-kB immune pathway's stimulation by the initial impact of vaccination,[41] causing inflammation elsewhere in the body sufficient to impact the ear. *Id.* at *9, 12. Indeed, it was deemed a "good candidate for explaining the clinical characteristics of idiopathic sudden hearing loss," and accepted as reasonable by Respondent's expert (although he did not also believe the flu vaccine could trigger it). *Id.* at *13. Items of literature also filed in this case and referenced in *Madigan* include Masuda and Merchant.

The special master in *Madigan* further accepted the petitioner's argument, supplemented by literature, that vaccination can increase circulating cytokine levels that could travel to the ear and cause harm, rejecting Respondent's expert's invocation of Baxter on the grounds that (a) its findings with respect to a lack of vaccine association were less robust for longer time intervals, and (b) its onset determinations had not (in the estimation of Petitioner's expert) been sufficiently confirmed. *Madigan,* 2021 WL 3046614, at *15–17. Also notable in *Madigan* was the fact that vaccine causation had treater support, and other lab work findings were consistent with the stress response theory. *Id.* at *18–19.

Madigan unquestionably offers positive parallels for Petitioner herein. But it is distinguishable in one significant respect that greatly deflates its utility as a guideline: the *Madigan* petitioner did not possess so glaring an alternative explanation for his hearing loss (an acoustic neuroma). I also do not find its causation theory to be compelling, reliable, or persuasive. I have

[41] Thus, it was not contended in *Madigan* that the flu vaccine's antigenic components sparked an autoimmune process (mediated by an adaptive, secondary immune response) leading to loss of hearing. *Madigan,* 2021 WL 3046614, at *13. The same is true in this case.

on many occasions considered theories asserting a vaccine-caused, cytokine-driven process led to injury, but have repeatedly deemed such theories wanting, absent evidence connecting the process (no matter how scientifically plausible it might be) with additional proof sufficient to render it "more likely than not" that the immune processes outlined could be rendered pathogenic by introduction of a vaccine. Otherwise, such a theory only attempts to transmute the expected reaction to a vaccine into pathology. *Dean v. Sec'y of Health & Hum. Servs.*, No. 13-808V, 2017 WL 2926605, at *17 (Fed. Cl. June 9, 2017). What was accepted in *Madigan* reads the same as what I have so often confronted, but rejected, in prior cases.

At best, then, *Madigan* establishes merely that there is disagreement among the special masters as to the association of hearing loss with the flu vaccine—*not* that the stress response theory has been sufficiently discussed or tested by prior decisions to deem it sufficiently valid to be embraced in this matter without scrutiny.

II. Petitioner Has Not Carried his Causation Burden of Proof

A. *Shyface* and Alternative Cause/"Factor Unrelated" Burden

The Remand Order requires that I perform a more detailed causation analysis in two respects: a *Shyface* evaluation of whether the flu vaccine could be deemed a "substantial factor" in causing Petitioner's SNHL, *even if* Petitioner's neuroma could be (and here was) also likely causal; and whether (assuming Petitioner's prima facie causation burden was met) Respondent preponderantly carried his shifted burden of establishing that the neuroma was the "factor unrelated" to vaccination that caused the injury. These inquiries are not congruent, and occur at different stages of the overall causation analysis.

1. *Shyface* – *Shyface* predates *Althen* by six years, and does not stand as an independent analytic framework for entitlement. Rather, its core legal pronouncement—that claimants must demonstrate a vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury" (*Shyface,* 165 F.3d at 1352–53)[42]—is consistent with the Circuit's embrace of the *Althen* causation prong framework applicable to non-Table cases (and effectively subsumed into *Althen*). Thus, although *Shyface's* language is often cited in Program decisions, it is not a separate or additional bar that claimants must clear to receive damages.

[42] As noted in *Fadelalla v. Sec'y of Health & Hum. Servs.,* No. 97-573V, 45 Fed. Cl. 196, 197 n.3 (1999), the Circuit looked to the Restatement (Second) of Torts to create the method of analysis set forth in *Shyface,* ultimately embracing the Restatement's conception that "a particular factor does not have to be the sole or predominant cause of harm in order to be a 'substantial factor'" (*citing Restatement (Second) of Torts* § 430 cmt. d (1963-64)).

In my experience, *Shyface* reasoning applies mainly under a specific set of narrow circumstances: when the parties largely agree that two causes for an injury (including a vaccine) exist, but where it cannot be ascertained which of the two best preponderantly "explains" the injury. In such a case, *Shyface* instructs the special masters only to ascertain if the vaccine could have been a substantial factor in causing the injury. *See, e.g.*, *Torday v. Sec'y of Health & Hum. Servs.,* No. 07-372V, 2009 WL 5196163 (Fed. Cl. Spec. Mstr. Dec. 10, 2009) (flu vaccine deemed causal of Guillain-Barré syndrome ("GBS")).

In *Torday*, former Chief Special Master Golkiewicz was faced with two causal explanations for a claimant's GBS—the flu vaccine or an intercurrent upper respiratory infection. *Torday,* 2009 WL 5196163, at *3. Both sides' experts agreed the vaccine *and* the infection could have been the reason for the injury, with no way to distinguish which predominated causally. Chief Special Master Golkiewicz decided the claim for the petitioner, since Petitioner's expert had affirmatively maintained that the nature of the infection was unknown, and that not all respiratory infections were associated with GBS (even if *some* were). *Id.* at *4–5.[43] This left the vaccine as a likely substantial factor, despite the undisputed existence of the infection.

2. Factor Unrelated/Alternative Cause – After a claimant successfully establishes a prima facie case of causation, "the burden then shifts to the government to prove alternative causation by a preponderance of the evidence." Section 13(a)(1)(B); *Cedillo,* 617 F.3d at 1338; *Schilling v. Sec'y of Health & Hum. Servs.*, No. 16-527V, 2022 WL 1101597, at *21 (Fed. Cl. Spec. Mstr. Mar. 17, 2022). The Vaccine Act defines "factors unrelated to the administration of the vaccine" to be matters "documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents *principally responsible for causing* the petitioner's illness, disability, injury, condition, or death." Section 13(a)(2)(B) (emphasis added).

The Respondent's burden in this context is distinguishable from what a petitioner must meet. As noted by the Court in *Stone v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 233, 237 (2010),

> the standard for proving a "factor unrelated" is higher than the petitioner's burden of proving a prima facie case. Although a petitioner is required to show that the vaccine was a "substantial factor" in causing his or her injury, "the petitioner need not show that the vaccine was the sole or predominant cause of her injury." (*de Bazan,* 539 F.3d at 1351). The respondent's burden, by contrast, is to "identify[ ] a particular [unrelated] factor (or factors) and present [ ] sufficient evidence to establish that it was the *sole substantial factor*

[43] *Torday* does not explicitly cite *Shyface,* but it does reference a number of post-*Shyface* Federal Circuit decisions that incorporate *Shyface's* substantial factor reasoning. *Today,* 2009 WL 5196163, at *5.

in bringing about the injury." *Id.* at 1354 (emphasis added). In order to prevail, therefore, the respondent must "exclude[ ] the vaccine as a substantial factor." *Id.*

The *Stone* panel went on to observe that "[t]he difference between "substantial factor" and "sole substantial factor" is a meaningful one," noting that compensation could still be awarded even in cases where a factor unrelated had been shown to be substantial—but not "solely" substantial. *Stone,* 95 F.3d at 237 n.5 (citations omitted). Thus, the obligation placed on Respondent to prove a factor unrelated goes beyond what a petitioner need show under *Shyface*—and, as *Stone* explains, actually shines light on the nature of the *Shyface* inquiry (since Petitioner's prevail in a "two cause" case even when they cannot prove the vaccine was the main cause of injury).

Importantly, the additional duties placed on Respondent in proving factor unrelated do not also include imposition of a heightened evidentiary burden. The evidence deemed *sufficient* to conclude that the factor unrelated burden has been carried must only be *preponderant*—Respondent is no more obligated to prove factor unrelated to a degree of certainty that a petitioner is when offering evidence on the *Althen* prongs. Thus (under the "fifty percent and a feather" colloquial summation of the preponderance standard), Respondent can prove a factor unrelated caused an injury, to the exclusion of the vaccine, *even* if some doubt persists as to whether it is *certain* the vaccine was not also causal.

In practice, special masters have found the factor unrelated burden was met based on the same mix of evidence and weighing of items of literature versus expert testimony that occurs when evaluating a petitioner's initial, prima facie success. Thus, to give one example, in *Stone* (where Respondent maintained that a child's Dravet syndrome was solely due to a genetic mutation rather than vaccination) the Court found that the special master had applied the wrong evidentiary standard in evaluating factor unrelated, remanding the case so the analysis could be performed again. But on remand, the special master was readily able to conclude that Respondent had met his burden, relying on a showing that included (a) the determination to give more weight to Respondent's expert testimony than Petitioner's, (b) the highly persuasive evidence of the alternative cause, and (c) an absence of record evidence that the vaccine *itself* had caused any harm to the child's brain (as would needed to have been shown to conclude the vaccine caused injury in accordance with the theory alleged). *Stone v. Sec'y of Health & Hum. Servs.,* No. 04-1041V, 2011 WL 836992. at *3 (Fed. Cl. Spec. Mstr. Jan. 20, 2011), *mot. for review den'd*, 99 Fed. Cl. 187 (2011), *aff'd,* 676 F.3d 1373 (Fed. Cir. 2012).

Even where two competing causes are accepted as likely, *Shyface* does not preordain a favorable outcome for the petitioner. The *Torday* fact pattern, with some slight adjustments, provides a good hypothetical example. Suppose a claimant alleged the flu vaccine had caused him to experience GBS—but the record evidence also showed the claimant had experienced a *Campylobacter jejuni* bacterial infection around the time of vaccination, as well. Both are causal

of GBS[44]—but in a case where onset was somewhat delayed, with no evidence of any vaccine-induced inflammation, but also where evidence of the effects of the bacterial infection was significant and closer-in-time to GBS onset, *Shyface* would not mandate entitlement simply because *Althen* prong one had been unquestionably established. In such a case it might not be found preponderantly established that the vaccine *was* a substantial factor—and the vaccine-GBS association could not undue what the medical record suggested had more likely occurred.

3. *Shyface*/Factor Unrelated Interaction – A final comment is warranted about how *Shyface* relates to a Respondent's factor unrelated burden. In effect, *Shyface* requires that a successful prong one showing has been made, since the vaccine must first have been demonstrated to be capable of causing injury. It therefore is evaluated in the context of *Althen*'s second, "did cause" prong—and a matter upon which *the petitioner bears the burden of proof*, measured by the preponderance standard. *Broekelschen v. Sec'y of Health & Hum. Servs.,* 89 Fed. Cl. 336, 346 (2009), *aff'd*, 618 F.3d 1339 (Fed. Cir. 2010); *see also Pafford,* 451 F.3d at 1356 ("[m]ost importantly, the second prong of the Special Master's test in this case restates correctly that the petitioner must show that the vaccine was the 'but for' cause of the harm according to *Shyface*, or in other words, that the vaccine was the 'reason for the injury' as stated in the second prong of the *Althen* test."). The burden to prove factor unrelated does not shift to Respondent *until* a prima facie case has been met.

In addition, even though petitioners are not affirmatively required to eliminate alternative causes, evidence in the record of explanations for an injury that undercut vaccine causation *can* be evaluated as part of the prong two analysis. Such evidence need not be ignored or tabled for some later point in time. *Broekelschen,* 89 Fed. Cl. at 346-47 (*citing Althen,* 418 F.3d at 1278 ("[t]he government, like any other defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief"). Petitioners must make some effort to confront a record that suggests a non-vaccine explanation for an injury if they wish to prevail on the "did cause" prong, even if they are not tasked with wholly *disproving* it as part of their prima facie case.

B. *Althen* Prong One

Petitioner has offered a science-heavy theory with many reliable components. The NF-kB immune complex, for example, could theoretically be disrupted by cytokine-promoting events, and it is possible an inflammatory environment specific to the ear could later (and rapidly) produce hearing loss. In addition, there is reliable support for the contention that active viral infections could also play a role in hearing loss. *See* McKenna, Miller. Some items of literature note that vaccines, including the flu vaccine, cause upregulation of a variety of cytokines. I do not deem the

[44] *See Bielak v. Sec'y of Health & Hum. Servs.*, No. 18-761V, 2023 WL 35509, at *30 (Fed. Cl. Spec. Mstr. Jan. 3, 2023).

majority of items of literature offered to be unreliable (even if many base conclusions on small sample sizes, or do not involve hearing loss at all). And Petitioner's causation theory was deemed sound and reliable in at least one prior case (although as noted, I do not find its reasoning persuasive). *See Madigan,* 2021 WL 3046614, at *17. It was also demonstrated by Petitioner that a *different* vaccine (the MMR) might be associated with SNHL. *See* Asatryan.

Such evidence must, however, be weighed against the numerous deficiencies in the theory's specifics. As already noted, there is an overall lack of evidence suggesting any association between the wild flu virus *or* flu vaccine and hearing loss, other than case reports (which are routinely, and reasonably, deemed deserving of limited weight). *See, e.g.*, *Pearson v. Sec'y of Health & Human Servs*., No. 17-489V, 2019 WL 1150044, at *11 (Fed. Cl. Spec. Mstr. Feb. 7, 2019) (concluding that case reports receive only limited evidentiary weight and cannot cure *Althen* prong one deficiencies); *Harris v. Sec'y of Health & Human Servs*., No. 10-322V, 2014 WL 3159377, at *18 (Fed. Cl. Spec. Mstr. June 10, 2014) ("case reports are generally not a valuable form of evidence"). Petitioner was thus tasked with offering a theory that connected several smaller contentions into a compelling and persuasive theory. He did not succeed, no matter the detail of his theory.

First, the proposition that hearing loss might be immune-mediated in some contexts does not mean a vaccine's *general* stimulation of the immune system is likely pathogenic in this specific way. This kind of argument rests on a faulty logic common in Program cases: if vaccines stimulate the immune system, *and* there is a possible immune-mediated pathogenic explanation for an injury, then the *expected* immune process can also turn pathogenic in susceptible individuals. *See, e.g.*, *Olson v. Sec'y of Health & Human Servs*., No. 13-439V, 2017 WL 3624085, at *20 (Fed. Cl. Spec. Mstr. July 14, 2017) (deeming it speculative to purport that cytokine upregulation due to a vaccine "would be robust enough, and occur for long enough, to be pathogenic generally, let alone to cause" the complained-of injury), *mot. for review den'd*, 135 Fed. Cl. 670 (2017), *aff'd*, 758 F. App'x 919 (Fed. Cir. 2018). In order to elevate such a theory beyond the merely plausible, however, a petitioner must connect it with evidence that suggests that at least the analogs for a vaccine's antigenic components might be capable of triggering such a process; the fact that vaccines generally impact the immune system (and cause localized inflammation or stimulate cytokines that can initiate inflammation elsewhere in the body) is only the *starting point* for a successful theory.

Contentions about the NF-kB complex and its speculated, unproven association[45] with some forms of ear/hearing dysfunction thus required more substantiation if they were to be accepted as part of a pathologic explanation in this case linked to the flu vaccine. I have noted in other cases that even if the description of this immune complex/pathway is accurate, *and* that it can play a role in causing damaging inflammation under some circumstances, *that* does not also

[45] Dr. Monsell so admitted, and items of literature he heavily relied on (Adams, Merchant) for his theory also acknowledge the lack of confirmatory research or findings. Opp. at 11–12.

mean that *vaccines* can stimulate it sufficiently to produce a pathologic response. *See, e.g.*, *Schilling v. Sec'y of Health & Hum. Servs.,* No. 16-527V, 2022 WL 1101597 (Fed. Cl. Spec. Mstr. Mar. 17, 2022). The *Schilling* petitioner alleged an entirely different claim—that the flu vaccine had caused reactivation of a dormant varicella zoster virus ("VZV") infection. But his expert argued, among other things, that NF-kB, the "master regulator of inflammation," could activate cytokines responsible for inflammatory processes (and thus could reactivate a quiescent VZV infection). *Schilling,* 2022 WL 1101597, at *5–6. Respondent's counsel agreed this immune complex could play a role in an initial *infectious* process, but less likely would be prompted into a pathologic reaction in the wake of a vaccination. *Id.* at *8. I ultimately found that the petitioner's theory relied on speculation to assume that what was known about the NF-kB complex generally would apply in the context of vaccination, and rejected the theory. *Id.* at *19.

The same is true here, despite the distinguishable context of ear inflammation. At bottom, Petitioner's theory as articulated by Dr. Monsell proposes that the initial, innate response to vaccination (as it is not contended that the flu vaccine caused the production of antibodies that would, via an autoimmune mechanism, cross-react with self structures resulting in ear damage) would cause SNHL. I do not find this contention persuasive or sufficiently corroborated to deem vaccine causal, however. The presence of increased cytokines alone in a post-vaccine environment does not inherently mean pathology, no matter the reliable nature of speculation to that end. And as pointed out by Dr. Bigelow, the stress response theory embraced herein has not been corroborated in much (if any) subsequent literature or scientific studies, and has not been linked to the factual circumstances obtaining in this case.

Otherwise, Dr. Monsell offered several studies specific to other kinds of injuries (*see, e.g.*, Liuba, Carty, which considered cardiovascular injuries and the risks posed by vaccine-upregulation of cytokines). Items of literature more specific to the ear, like Masuda, Merchant and Adams, did not establish that SNHL is *only* or predominantly mediated by disruption of the NF-kB pathway, did not evaluate the extent to which a viral infection could cause this kind of immune interference (let alone vaccination), and were forthright in acknowledging their speculative or hypothetical aspects. However specifically reliable in the narrow context of their findings, their hypotheses have not been shown to have been corroborated with any additional studies sufficient to support the contention that vaccination could cause a pathologic interference with the NF-kB pathway leading to hearing loss.

Second, there is evidence in this case *directly undercutting* a vaccine-SNHL association—a large-scale epidemiologic study, Baxter, that reached statistically-reliable results, and observing that a flu-vaccinated population's incidence of hearing loss was not higher than an unvaccinated group. Baxter at 83. It is well understood in the Program that even if Petitioners are not *obligated* to offer epidemiologic evidence, this class of evidence can be considered when it exists and is relevant—as here. *See Perekotiy v. Sec'y of Health & Hum. Servs.*, No. 16-997V, 2020 WL

12904810, at *13 (Fed. Cl. Spec. Mstr. Apr. 20, 2020), *mot. for review den'd*, No. 16-997V, 2020 WL 5887548 (Fed. Cl. Sept. 17, 2020) (citing *Andreu*, 569 F.3d at 1378–79). The suggestion that, because Petitioners need not offer such direct evidence, it should be disregarded, is simply erroneous. And invocation of the rarity of vaccine injuries generally (and the concomitant difficulty for large scale studies to "see" them) amounts to a conclusory contention that would, if accepted, amount to lowering of a claimant's burden.

Certainly, Baxter does not wholly disprove the possibility of causation under Petitioner's theory. And some of its methodologic decisions could be picked apart or criticized (as they were in *Madigan*). Here, Dr. Monsell noted that Baxter's determination of risk in a two-week timeframe was not statistically significant—an accurate point, but one that failed to also note that the timeframe specific to *Petitioner's* experience (one week, since his onset occurred four days from vaccination) not only saw no vaccine-associated risk, but also did not possess the P-value limitations he identified for the longer period. Baxter at 84–85. Dr. Monsell's "power" criticisms were far less persuasive. Baxter considered millions of flu vaccine doses. Baxter at 83. Its topline determination has some core value, even if a better study was possible. Epidemiologic evidence cannot make it *impossible* that the flu vaccine could cause SSNHL, and I do not treat Baxter as a primary reason to find against vaccine causality. But its reliable findings make causation *less likely*—and for purposes of the preponderant evidentiary standard, that is what matters.

All in all, Petitioner's theory possessed a *degree* of medical and scientific plausibility, and it certainly is not frivolous or properly dismissed out of hand. But it lacks the links necessary to connect SSNHL to the flu vaccine's antigens or their counterpart wild viral components, while being undercut by direct evidence undermining the flu vaccine as causal. And Dr. Monsell's embrace of the theory did not gain strength or support from any personal research or study experience specific to the issues at hand that he could reference in giving his opinion. He was qualified to offer an expert opinion in this case, but he could not reference individual expertise considering the possible causes of SNHL, or the role vaccination might play.

I heard both experts testify live, and have re-reviewed their reports and the trial transcript as part of my Remand Order-designated task. I continue to conclude that Dr. Bigelow persuasively rebutted the causation theory Petitioner offered. In so finding, I act in full accordance with the role a special master plays when evaluating competing expert opinions:

> Expert opinion testimony is just opinion, and the fact-finder may weigh and assess that opinion in coming to her own conclusions. However, even more than ordinary fact-finders, this Court has recognized the unique ability of Special Masters to adjudge cases in the light of their own acquired specialized knowledge and expertise . . . The Special Master's sole professional responsibility for years has been to preside over vaccine cases . . . No judge or jury can be forced to accept or reject an expert's opinion or a party's theory at face value.

> To require such a choice in this context is to neglect the Special Master's duty to "vigorously and diligently investigate the factual elements" underlying the petition.

Sword v. United States, 44 Fed. Cl. 183, 188 (1999).

C. *Althen* Prong Two

1. *General "Did Cause" Analysis* – I also cannot find on the basis of this record that it is preponderantly likely the flu vaccine "did cause" Petitioner's hearing loss. First, and significantly, contemporaneous treater views weigh more in favor of the neuroma as the causal explanation. Ex. 9 at 13–14; Ex. 21 at 1–2; Ex. 26 at 5; Ex. 27 at 214. The consistent implication from the records is that Petitioner's treaters associated the neuroma with his SNHL, and deemed the monitoring of it to be a component of the SNHL treatment (as opposed to a distinguishable or unrelated matter). By contrast, although there are instances where the vaccine's temporal relationship to Petitioner's onset is mentioned, this more commonly occurred in the context of recording Petitioner's self-reported history (or repeating prior medical record information) than as evidencing a treater speculation of association. Ex. 9 at 14, 16, 18. Petitioner's treaters did not *opine* the vaccine was causal, even if they acknowledged the plain fact that his onset followed vaccination closely in time.

Petitioner has pointed to the future flu vaccine exemption he purportedly obtained (as reflected in Ex. 27 at 214) as proof that some treaters concurred as to the vaccine's likely causal role (since they believed he should not receive it again). However, direct record proof of this exemption has never been filed in this case, leaving only a single secondary *reference* to it as supporting it, coupled with Petitioner's at-trial testimony that he received the exemption. But even if I accept that proof of the exemption was preponderantly established based on the foregoing, I do not give it significant weight in this case (nor does prior Federal Circuit case law *compel* that result).[46] The evidence of the exemption, such as it is, does not permit a determination as to its basis, or if the treater or treaters who provided it also *discounted* the neuroma's role, let alone

[46] Petitioner cites *Andreu,* 569 F.3d at 1376, for the proposition that "the Federal Circuit has maintained that a treating doctor's recommendation to withhold a certain vaccination can provide probative evidence of a link between a vaccination and an injury the claimant has sustained." Br. at 26. But this merely means I should consider the evidence of an exemption—not that it is *per se* probative of treater views on causation, or merits more weight than other evidence. Indeed, the facts of *Andreu* underscore the circumstances in which it would be reasonable to give evidence of an exemption greater weight than here. There, the treater who provided the exemption at issue not only testified in the case, but explained the basis for the exemption. *Andreu,* 569 F.3d at 1376 ("[the treater] testified that although he was just being 'conservative,' he made this recommendation because 'there was a concern over the relationship [of the seizures] with the immunization, and I felt it would be safer for [injured party] not to have the pertussis, because there was a concern about a reaction'").

considered it. I am empowered to weigh such evidence in light of all evidence pertaining to the matter. This is not a case in which a vaccine exemption stands as persuasive proof of causality.[47]

Second, there is the indisputable existence of the acoustic neuroma. Its capacity to cause hearing loss is supported by far more robust and reliable evidence than evidence of vaccine causality offered in this matter. Aslan at 580 (". . . unilateral sensorineural hearing loss has been described as the classic symptom of the vestibular schwannoma . . ."); Saunders at 23 (". . . there have been numerous reports of SHL in acoustic neuroma (AN) patients."); Sauvaget at 592 (". . . SSHL is recognized as a revealing symptom of [vestibular schwannoma] and because a missed early diagnosis may jeopardize hearing and facial preservation and have liability implications. . . ."). Nor is there sufficient preponderant evidence from Petitioner's post-vaccination treatment history (a test result or reported symptom) that would support the vaccine as causal—other than the mere temporal relationship to the date of Petitioner's onset. At most, Petitioner alleges a largely-uncorroborated, transient reaction to vaccination, but nothing else from the contemporaneous records suggest an immune reaction leading to the presenting symptoms of Petitioner's SNHL (vertigo) was underway in the five days prior.

Petitioner's arguments that clinical evidence in the record undercuts the neuroma as causal are unpersuasive. He notes, for example, that neuromas are often asymptomatic—but this runs against Dr. Bigelow's more-persuasive point that neuromas are often only *discovered* once hearing loss suddenly manifests, which is what occurred in this matter. Tr. at 135–36. This also rebuts Petitioner's contention that his hearing loss should have begun pre-vaccination if the neuroma had caused it; the existence of the neuroma was not *known until hearing loss presented*. Petitioner also erroneously maintains that neuromas mostly cause progressive hearing loss, rather than SNHL. As Dr. Bigelow persuasively established, however, neuromas are *also* associated with sudden hearing loss—a contention the literature fully supports. Moffat at 116 ("Sudden deafness has long been known to be a manifestation of cerebellopontine lesions"); Pensak at 1188 ("physicians are cognizant of the fact that lesions of the cerebellopontine angle, primarily acoustic neuromas, may present with sudden hearing loss."); Lin at 842 ("Because of increasing widespread use of MRI, a

[47] I also note that, in the experience of the Vaccine Program, treaters often freely give exemptions as a patient accommodation, regardless of whether there is any serious/substantiated concern or ascertained relationship between the vaccine and an injury. *Morris v. Sec'y of Health & Hum. Servs.*, No. 13-601V, 2017 WL 2461226, at *15 (Fed. Cl. Spec. Mstr. May 9, 2017) (noting that petitioner's PCP agreed to provide a letter exempting her from future vaccination based in part on her prior experience, but the actual records in the case suggested that the PCP was skeptical of a connection between the vaccine and petitioner's injury). Here, Petitioner's status as a medical care professional may well have influenced the exemption decision, and played a greater role in the decision to permit exemption than the real risk of injury from a vaccine. Certainly, there is no "challenge-rechallenge" evidence in this case that the Petitioner previously experienced post-flu vaccine complications (thus giving credence to his having experienced a similar reaction after the vaccination at issue). *Nussman v. Sec'y of Health & Hum. Servs.*, No. 99-500V, 2008 WL 449656, at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 2008), *aff'd,* 83 Fed. Cl. 111 (2008). Thus, the mere fact of exemption (which has not even been sufficiently established evidentiarily in the first place) lacks probative weight absent evidence of the *context* in which it was obtained.

greater number of cases of [vestibular schwannoma] than expected were found in patients with SSNHL as their first symptom."). The size of Petitioner's neuroma was also not demonstrated to be a factor undercutting causality, with many items of literature establishing that a small size does not rule out complete hearing loss. Jeong at 3; Lin at 841–42; Aslan at 581–82.

Here, I am obviously evaluating evidence of the neuroma as a competing cause, in the context of determining Petitioner's success in proving the second *Althen* prong. While, as already noted, claimants are not *obligated to rule out* alternative causes as part of their initial prima facie showing, this does not mean (as the Federal Circuit has repeatedly observed) that compelling evidence of other explanations for an injury that are evident from the relevant medical record cannot be evaluated—and cannot in turn undermine a claimant's prong two showing. *Snyder v. Sec'y of Health & Hum. Servs.*, 553 F. App'x 994, 1000 (Fed. Cir. 2014) (" 'no evidence should be embargoed from the special master's consideration simply because it is also relevant to another inquiry under the statute' ") (*quoting Stone*, 676 F.3d at 1380); *see also de Bazan*, 539 F.3d at 1353. Special masters properly look at *all* evidence bearing on a claim—and that includes evidence relevant to the "did cause" prong, even if it might come into play at later stages of a case as well.

In this case, the neuroma is the "elephant in the room," and it cannot be reasonably be disregarded when evaluating whether Petitioner preponderantly established that the flu vaccine "did cause" his SNHL. The neuroma was discovered in the course of treating Petitioner's hearing loss; it continues to exist; and the medical records suggest that treaters viewed it as the best explanation for his SNHL (a determination supported by the filed medical literature). This evidence weighs against the comparatively-meager record evidence that the Petitioner's hearing loss was vaccine-caused, no matter how skillfully a plausible mechanism for causation was constructed. At bottom, the "best" evidence of a vaccine-injury association that can be mustered is the fact that hearing loss occurred within a week of vaccination. But without other proof, that kind of temporal showing is not and has never been enough of a basis for a favorable entitlement decision. *Grant,* 956 F.2d at 1148 ("[t]emporal association is not sufficient . . . to establish causation in fact").

2. *Shyface Analysis* – This is not a case in which the parties agree that the facts present two competing potential causes of hearing loss. Rather, while Dr. Monsell concedes acoustic neuromas may cause some kinds of hearing loss, Dr. Bigelow does not at all concede the flu vaccine as causal. Nor, as already noted, have I found that Petitioner preponderantly established that the flu vaccine can cause SSNHL—no matter how plausible or well-crafted Petitioner's stress response theory mechanism is. Thus, there is arguably no need for consideration, under *Shyface,* as to whether the flu vaccine could have been a substantial factor in actually causing Petitioner's SSNHL—whether in concert with the neuroma or regardless of it.

But assuming my *Althen* prong one determination was in error, I would still find that Petitioner had not carried his preponderant burden of proof on this aspect of the claim—even under the "substantial factor" framework. *Shyface*, 165 F.3d at 1352–53.

First, the record evidence preponderantly supports the conclusion that Petitioner's vestibular schwannoma was the *primary* factor in causing his hearing loss, with the vaccine's role lesser (if at all). Robust and persuasive evidence of the capacity of vestibular schwannomas/acoustic neuromas to cause SSNHL generally was offered—and even if I should have deemed the evidence of vaccine causation to be preponderant, it remains the case that the balance of evidence on this subject favors Respondent. The direct proof of causation offered by Respondent was more compelling. This balance of evidence tilts strongly against Petitioner at the outset; the fact that a vaccine "can cause" an injury does not mean, under *Shyface,* that the vaccine will always be a likely "substantial factor."

Second, the medical record itself does not suggest that the vaccine likely played a role in causing SSNHL herein. Although Petitioner claimed to have experienced some transient post-vaccination response, the evidence in this case is silent as to the presence of inflammation leading to hearing loss, with no testing result or clinical finding that could implicate the vaccine as having *some* role. By contrast, Petitioner's actual presentation was consistent with the neuroma being the primary, if not sole, cause of his SSNHL, despite Petitioner's contentions about neuromas.

Third, Petitioner has not offered much of an explanation for how the vaccine and the neuroma might have interactively produced hearing loss. Even if, under *Shyface,* Petitioner need only show the vaccine played a substantial role in causing the hearing loss at issue, the post-onset discovery of the neuroma, which Petitioner fully acknowledged existed, is a rather significant medical fact that warrants some acknowledgement and recognition. At most, Dr. Monsell suggested that the neuroma might merely have functioned akin to a "risk factor" that made hearing loss more likely. But his theory provided only sketchy proposals for how this would have occurred, other than opining that the neuroma could only contribute to hearing loss in an existing "inflammatory milieu" (presumably created by the flu vaccine's administration). Tr. at 98. Items of literature Petitioner relies on for his proposed stress response theory do not discuss how the theory would play out in the presence of a neuroma—and even acknowledge hearing loss could occur via *other* mechanisms. *See, e.g.*, Merchant at 158–59 ("[o]ur hypothesis is not meant to account for all cases of [SNHL]"). A finding that the vaccine played some important role in Petitioner's SNHL would have been aided by persuasive evidence explaining the neuroma's synergistic interaction with the stress response theory—but that concept was inadequately developed.

I also do not find that the neuroma was simply a comorbid "risk factor," that played some background contributory role. Dr. Monsell noted that other conditions (high blood pressure and

obesity, for example) were not only also SNHL risk factors, but possessed by Petitioner. Tr. at 71, 84; Monsell First Rep. at 5; Mosnier at 62–64. Had there been no acoustic neuroma at all, I would have had no trouble finding under *Shyface* that these admitted additional risk factors did not rebut the conclusion that the vaccine was *also* a substantial factor (again—ignoring my finding that the vaccine was not shown to be capable of causing SNHL), even if it could not be teased out what factor was predominantly causal. The medical record does not substantiate Petitioner's baseline health as most explanatory for his injury—no treaters, for example, so concluded, and the record does not detail enough facts about them to draw conclusions. But *the record does preponderantly establish that the neuroma was more likely causative*—over not only the vaccine but also these other comorbid factors, as well.

C. *Althen* Prong Three

Petitioner's third prong/timeframe showing, by contrast, was more persuasive. Petitioner's four-day, post-vaccination onset was not disputed, and that timeframe is consistent with his theory about how long an aberrant cytokine-driven process attributable to an innate immune response would take to occur. Reliable science bulwarks it, and it is also consistent with the timeframe deemed medically acceptable in the few other favorable decisions involving hearing loss. *Madigan,* 2021 WL 3046614, at *20 (finding that a three-to-four-day onset was reasonable). Of course, Baxter suggests that if in fact there is any flu vaccine-SNHL risk at all, it does not come into play within a week's time post-vaccination (since the odds ratio for that period was exceedingly low), but later. Baxter at 84–85. Nevertheless, I find for Petitioner on this aspect of his claim (and give this aspect of Baxter a little less weight than I do its ultimate conclusion about the lack of vaccine association).

III. Even if Petitioner Had Established a Prima Facie Causation Case, Respondent Has Carried His Alternative Cause Burden

The evidence in this case robustly supports the conclusion that Petitioner's acoustic neuroma/vestibular schwannoma was the most likely cause of his SNHL. Reliable evidence was offered to establish that acoustic neuromas frequently result in sudden, acute hearing loss. Moffat at 117; Pensak at 1188; Saunders at 26; Sauvaget at 593. Far more of this kind of evidence was offered than evidence associating the flu vaccine to sudden hearing loss. Indeed, the literature, and Dr. Bigelow's testimony, establishes that the very manifestation of SNHL is an occasion to see if a neuroma is present (thus indirectly bulwarking a causal relationship). Aslan at 581 ("[i]t has long been recognized that [sudden hearing loss] may be a harbinger of [vestibular schwannoma]").

Dr. Monsell for his part did not deny a potential causal relationship between sudden SNHL and the discovery of an existing vestibular schwannoma. *See* Tr. at 63, 91–92. Dr. Bigelow, by contrast, was steadfast in supporting the neuroma over vaccine as casual, and I afford his opinion greater weight after hearing from both experts, even if their credentials and competence to offer

an opinion were roughly equal. Tr. at 108–09; Bigelow First Rep. at 11; Bigelow CV at 5–18. Dr. Bigelow also persuasively established, over Dr. Monsell's counterargument, that in this case the small size of the tumor was irrelevant—and in fact *more* likely to produce hearing loss than a larger one. Jeong at 3; Lin at 841–42; Aslan at 581–82. And Dr. Monsell's other efforts to diminish the likely role of the neuroma in causing Petitioner's SNHL were unpersuasive.

Respondent also was able, through a preponderant evidentiary showing, to *exclude* the flu vaccine as likely causal of Petitioner's SNHL. The scientific literature offered to associate the vaccine with SNHL, under a stress response theory, largely embraced the concept that immune stimulation could trigger an aberrant reaction in the ear—but without sufficient corroborative proof to find it likely that this can occur in the context of a single vaccine's administration. Dr. Monsell could not effectively leverage his expertise on the topic to fill gaps in the theory, and he did not demonstrate that he possessed personal knowledge of hearing or auditory issues impacted by an immune-stimulating pathogenic process, such that the causation opinion he offered should be given extra weight; rather, like many experts, his opinion, and the literature offered, seemed to be the product of the needs of the claim (and thus literature filed in the case was researched for it specifically). And the medical record strongly points to the neuroma—not the vaccine—as causal, with almost nothing *other* than Petitioner's theory and some recorded instances of *Petitioner* reporting an association, to support a connection. It is *highly* unlikely the flu vaccine had anything to do with Petitioner's hearing loss, despite the timing in which that loss was experienced.

The neuroma's likely and primary causal role in Petitioner's SNHL is not eliminated simply because the *mechanism* by which an acoustic neuroma causes hearing loss is not fully understood (whereas Petitioner has offered an immune-mediated mechanism).[48] Proof of mechanism is *never* an affirmative evidentiary requirement placed on either party—although (as I have observed in prior cases) claimants often seek to propose a mechanism for how a vaccine results in injury to bulwark their theories, making it a reasonably-considered issue. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26); *See also Trollinger v. Sec'y of Health & Hum. Servs.*, No. 16-473V, 2023 WL 2521912, at *30 (Fed. Cl. Spec. Mstr. Feb. 17, 2023), *appeal docketed*, No. 16-473V, (Fed. Cl. Mar. 17, 2023) ("Although Program claimants are not *required* to propose a mechanism, they often attempt to do so—and thus invite scrutiny into whether the proposed mechanism has preponderant support."). Regardless, evidence of mechanism does not per se outweigh evidence of *direct causation*; indeed, in almost any case a petitioner would *prefer* to offer direct proof of causation

[48] It is not entirely correct that Respondent conceded he could not prove a mechanism for acoustic neuroma-caused SNHL, even if Dr. Bigelow admitted that medical science has not fully explained why neuromas produce hearing loss. To the contrary, literature filed in this case speculates as to several possible explanations. *See, e.g.*, Sauvaget at 594 (listing four possible mechanisms specific to the impact of a vestibular schwannoma); Aslan at 582. And Dr. Monsell did admit that even under his theory, much was unknown about the processes leading to hearing loss. *See, e.g.*, Monsell Second Rep. at 1. But I do not contest that the evidence Petitioner offered on the subject of mechanism was more detailed and robust than what Respondent offered.

(e.g., a study showing a particular vaccine is associated with a specific injury) but cannot find it (and the Program takes into account that difficulty by allowing a large variety of indirect and circumstantial evidence to be offered to prove entitlement).

In this case, Respondent has offered *robust and direct evidence*—not disputed in the main by Dr. Monsell (even if he downplays it)—of a neuroma's capacity to cause SSNHL. Petitioner has no comparable evidence supporting flu vaccine causality, and there is in fact reliable epidemiologic evidence *diminishing* the likelihood of a flu vaccine association. Given the balance of evidence, it in no way weakens the otherwise-demonstrated neuroma-SSNHL association to note that no mechanism for injury was offered by Respondent.

Petitioner's other efforts to discount the neuroma's role are unpersuasive, and reflect the kinds of arguments that are generally disregarded when presented by *Respondent* in the context of a typical *Althen* analysis. For example, Petitioner emphasizes that "the presence of an acoustic neuroma is not dispositive of hearing loss." Reply at 11. Of course, the same is true of vaccination—receipt of the flu vaccine before an injury is not dispositive of causation either—and this is why I have carefully considered the evidence offered to ascertain if neuromas *can be* associated with sudden hearing loss presenting acutely (in addition to progressive or slower loss). The answer is yes. *See, e.g.*, Aslan at 581; Jeong at 5 ("[t]he most commonly observed MRI abnormality in patients with SSNHL was vestibular schwannoma, and all of the lesions were small or medium-sized tumors involving the [internal auditory canal]"). The general safety of the flu vaccine would not be probative of its capacity, or lack thereof, to cause injury—and the fact that *many* neuromas do not lead to SNHL does not mean that preponderant evidence establishes that *some* do.

In parallel fashion, Petitioner also seeks to discount the incidence of acoustic neuromas associated with SNHL (in comparison with progressive forms of hearing loss). Reply at 11. Thus, he notes that Lin only observed a low prevalence (two out of 10,000 people). Lin at 841. But this only speaks to the rarity of this kind of injury—*not* that the neuroma is not likely causal of it in these rare circumstances. *Id.* ("[t]here are usually sporadic and unilateral tumors showing SSNHL as the first symptoms of vestibular schwannoma patients"). Usually, Program *petitioners* argue that the rarity of vaccine injury should be taken into account when weighing the strength of a causation showing;[49] here, Petitioner wants rarity to do the work of eliminating an otherwise self-evident explanation for the injury at issue.

[49] Indeed, in many cases it is observed that injuries widely understood to be vaccine-associated, like GBS after the flu vaccine, occur only in 1 out of *100,000* doses. *Sweeney v. Sec'y of Health & Hum. Servs.*, No. 13-392V, 2020 WL 1844672, at *16 (Fed. Cl. Spec. Mstr. Feb. 28, 2020). But that statistic does not undermine causation.

Thus, given the above I readily find Respondent has preponderantly established that Respondent met his factor unrelated burden of proof.[50]

CONCLUSION

On remand, I have attempted to leave no stone unturned in detailing the bases for my determination. I could have penned even more pages. But my determination is the same as before. Preponderant evidence does not support Petitioner's causation theory, and it is not preponderantly likely the flu vaccine was a substantial factor in causing Petitioner's hearing loss. Otherwise, Respondent amply and robustly carried his shifted burden of proof of a factor unrelated—*and* that the vaccine could be wholly excluded as causal. Petitioner is thus not entitled to compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[51]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[50] Petitioner maintains in passing in his Reply that Respondent has not also met the third *Althen* prong on his factor unrelated showing—that a medically acceptable timeframe passed between onset of Petitioner's SNHL and the neuroma. Reply at 10–11. But it may be both unreasonable and unworkable to attempt to rigidly apply that prong in the context of the relevant factor unrelated. Unlike a vaccine, the precise time and date a neuroma (which is not "administered" to a patient, thereby introducing something foreign into the body and "starting the clock" for a pathogenic process under a causation theory) "began" is almost unknowable, such that it could be calculated by medical science when it would first likely cause clinically-evident symptoms. And in any event, as has now been discussed at length in this Decision, many of the filed articles establish that a neuroma/vestibular schwannoma can be *retroactively identified* in the presence of sudden hearing loss. *See, e.g.*, Sauvaget at 592 ("[SNHL] is recognized as a revealing symptom of [a vestibular schwannoma] and because a missed early diagnosis may jeopardize hearing and facial preservation and have liability implications. . . ."); Pensak at 1188 ("physicians are cognizant of the fact that lesions of the cerebellopontine angle, primarily acoustic neuromas, may present with sudden hearing loss"). I can thus conclude from this record, and such literature, that the suddenness of Petitioner's hearing loss was consistent with the time a neuroma would become sufficiently fulminant to cause SNHL.

[51] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.